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Effectiveness and safety of surgical procedures to treat apical prolapse - Comparison of sacrospinous fixation, laparoscopic sacrocolpopexy/sacrohysteropexy, and the Manchester procedure

Möller A, Campbell J, Forslund M, Hognert H, Rosenberg E, Ödesjö E, Hongslo Vala C, Stadig I, Strandell A, Svanberg T, Wartenberg C

VÄSTRA GÖTALANDSREGIONEN
SAHLGRENSKA UNIVERSITETSSJUKHUSET

Effectiveness and safety of surgical procedures to treat apical prolapse - Comparison of sacrospinous fixation, laparoscopic sacrocolpopexy/sacrohysteropexy, and the Manchester procedure

[Effektivitet och säkerhet av kirurgiska behandlingsmetoder vid apikal prolaps. En jämförelse av vaginal sakrospinosusfixation, laparoskopisk sakrokolpopexi/sakrohysteropexi och vaginal Manchesteroperation]

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1. Abstract

Background
Apical prolapse is a descent of the uterus, cervix or vaginal vault which can be associated with symptoms such as vaginal bulging, voiding or defecatory dysfunction. On a yearly basis around 1750 women undergo surgery for apical prolapse in Sweden, about 130 of these at Sahlgrenska University Hospital (SU). The majority of the women at SU are treated by transvaginal sacrospinous ligament fixation (SSLF) in case of previous or concurrent hysterectomy or sacrospinous hysteropexy (SSHP) if the uterus is spared. Another transvaginal method is the Manchester procedure implying cervix amputation and fixation to uterosacral ligaments. Increasingly, laparoscopic sacrocolpopexy (LSC) in case of previous or concurrent hysterectomy or laparoscopic sacrohysteropexy (LSH) if the uterus is spared is offered. In this method, a mesh is attached between uterus/the vaginal vault and the ligament over the promontory. Laparoscopic treatment can also be conducted with robot assistance, Robotic assisted sacrocolpopexy (RASC) or Robotic assisted sacrohysteropexy (RASH).
The choice of surgical method varies considerably across Sweden.

Question at issue
In women receiving surgical treatment of apical prolapse, how do the three surgical methods sacrospinous fixation (SSF), laparoscopic sacrocolpopexy/sacrohysteropexy (LSC/LSH) and Manchester-procedure - compare regarding benefits, risks, and costs?
Outcomes critical for decision making: Health related quality of Life (HRQL), awareness of prolapse, patient satisfaction, reoperation, recurrent prolapse. Outcomes important for decision making: dyspareunia, chronic pain, patient-reported tolerance of physical load, and urinary incontinence. Other outcomes: operative time, length of hospital stay, and duration of sick leave. Further, information on complications in connection with the three surgical methods.

Methods
Two authors performed searches (April 2021) in PubMed, Embase, the Cochrane Library, Cinahl, Amed, PsycInfo, and a number of HTA-databases. They independently assessed the abstracts, and selected, in consensus, full-text articles to be sent to the other authors, who then decided in consensus on inclusion/exclusion. Included controlled studies were critically appraised, and data from all included publications were extracted. Certainty of evidence was assessed according to GRADE.

Results
38 studies were included. One randomised controlled trial (RCT) and five cohort studies comparing SSF with LSC/LSH, one cohort study comparing SSF with the Manchester procedure, and 31 case series evaluating complications for one of the three surgical methods.
Sacrospinous fixation (SSLF/SSHP) vs laparoscopic sacrocolpopexy/sacrohysteropexy (LSC/LSH)
One RCT with some limitations in directness, and risk of bias and five cohort studies compared these treatments. *HRQL* was reported in the RCT and in one cohort study with no significant differences in the overall HRQL, yet slightly better results in a urogenital distress inventory score after sacrospinous fixation than after laparoscopic sacrocolpopexy/sacrohysteropexy. Regarding *patient satisfaction, reoperation, relapse,* and *urinary incontinence* no significant differences were reported, and it is concluded that there may be little or no difference between the two methods (GRADE ⊕⊕◯◯). Due to further limitations in the precision of studies presenting data on *awareness of prolapse, dyspareunia, chronic pain* and *length of hospital stay* it is uncertain whether there is a difference between the two treatments in these outcomes (GRADE ⊕◯◯◯). *Operative time* was substantially shorter for sacrospinous fixation than for laparoscopic surgery in all three cohort studies with this outcome. Thus, sacrospinous fixation may imply a shorter operative time than laparoscopic surgery, yet the extent of difference is uncertain (GRADE ⊕⊕◯◯).
Patient-reported tolerance of physical load, and *duration of sick leave* have not been reported in comparative studies of these methods.

Sacrospinous fixation (SSF) vs Manchester procedure
Based on one cohort study it is concluded that sacrospinous fixation may imply a higher risk of reoperation than the Manchester procedure, yet the magnitude of difference is uncertain (GRADE ⊕⊕◯◯). No comparison of sacrospinous fixation and Manchester procedure for other outcomes were found.

Laparoscopic sacrocolpopexy/sacrohysteropexy (LSC/LSH) vs Manchester procedure
No studies were identified.

Complications reported in several studies of sacrospinous fixation include pelvic, thigh or gluteal pain and urinary tract complications, such as difficulty voiding or urinary tract infections. Several studies of laparoscopic sacrocolpopexy/sacrohysteropexy reported cases of venous thromboembolic complications (frequency of 0.1% to 0.4%), surgical site infections (frequency of 0.4% to 1.4%), and urinary tract infections (frequency of 3.1% to 3.6%). For the Manchester procedure, several studies reported complications of urinary retention (frequency of 2% to 22%).

Costs
According to a database of costs per patient in VGR in 2019 and 2020, the average cost per patient treated with sacrospinous fixation was 66 500 SEK, for laparoscopic treatment 117 800 SEK and for the Manchester procedure 43 300 SEK.

Conclusion
There are seven studies comparing surgical methods of interest for this HTA-report. The studies comparing sacrospinous fixation and laparoscopic sacrocolpopexy/sacrohysteropexy (LSC/LSH) indicate that there may be little or no difference between these treatments regarding overall HRQL, patient satisfaction, reoperation, relapse, and urinary incontinence. Yet, sacrospinous fixation may imply shorter operative time and may lead to slightly less urogenital distress. For other important outcomes, the available data are insufficient for any inference.
Comparative information on sacrospinous fixation and Manchester procedure is limited to one cohort study indicating that reoperation may be less frequent after the Manchester procedure.
Currently, no studies comparing laparoscopic sacrocolpopexy/sacrohysteropexy (LSC/LSH) vs the Manchester procedure are available.
Regarding risks, urinary tract complications were seen after all three methods. In addition, pelvic, thigh, and gluteal pain were reported after sacrospinous fixation. Cases of venous thromboembolic complications and surgical site infections were seen after laparoscopic sacrocolpopexy/ sacrohysteropexy.

2. Svensk sammanfattning – Swedish summary

I denna HTA-rapport har vi utvärderat tre kirurgiska behandlingsmetoder för apikal prolaps (framfall av vaginaltoppen/livmoder) – **A.vaginal sakrospinosusfixation** (vaginaltoppen sys mot ett bäckenligament)**, B. laparoskopisk sakrokolpopexi/sakrohysteropexi** (titthålskirurgi där livmoder/vaginaltopp med hjälp av ett nät sys mot ligamentet på framsidan korsbenet)**, och C. vaginal Manchesteroperation** (livmodertappen förkortas och ligamenten förstärks) –avseende hälsorelaterad livskvalitet, patientnöjdhet, re-operation, återfall, symtom av prolaps, långvarig smärta, samlagssmärta, urininkontinens, operationstid, vård- och sjukskrivningstid, patientrapporterad tolerans för fysisk belastning, samt komplikationer. Vi har även sammanställt information om kostnader för dessa behandlingsmetoder.

Bakgrund
Varje år genomgår ca 130 kvinnor en operation för apikal prolaps (framfall av vaginaltoppen/ livmoder) vid Sahlgrenska Universitetssjukhuset. Operationsmetoden varierar: den för närvarande vanligaste metoden är vaginal sakrospinosusfixation (med eller utan samtidig eller tidigare borttagning av livmodern). Det näst vanligaste ingreppet är en vaginal metod kallad Manchesteroperation. På sistone har andelen titthålskirurgiska ingrepp, laparoskopisk sakrokolpopexi/sakrohysteropexi, med nät som fästs mellan livmoder/vaginaltopp och ligamentet på framsidan av korsbenet (med eller utan samtidig eller tidigare borttagning av livmodern) ökat. Det titthålskirurgiska ingreppet kan utföras robot-assisterad. Valet av kirurgisk metod varierar över landet.

Metod
Med hjälp av etablerade metoder identifierade vi de vetenskapliga artiklar som har utvärderat de kirurgiska metoderna. Vi granskade de enskilda studiernas kvalitet och bedömde tillförlitligheten i de sammanlagda resultaten enligt GRADE-systemet.

Resultat 38 studier inkluderades. En randomiserad kontrollerad studie och fem icke-randomiserade kontrollerade studier som jämförde sakrospinosusfixation med titthålskirurgi, samt en icke-randomiserad kontrollerad studie som jämförde sakrospinosusfixation med Manchesteroperation. 31 fallserier ger information om komplikationer vid någon av de tre kirurgiska metoderna.
Sakrospinosusfixation vs titthålskirurgi
Metoderna jämfördes i en randomiserad kontrollerad studie med vissa brister i överförbarhet och studiekvalitet, samt fem icke-randomiserade kontrollerade studier. Inga signifikanta skillnader avseende patientnöjdhet, re-operation, återfall, urininkontinens eller hälsorelaterad livskvalitet rapporterades, dock noterades något bättre resultat i ett frågeformulär om urinvägsbesvär samt kortare operationstid vid sakrospinosusfixation i studien. För alla dessa utfall bedömdes tillförlitligheten till det vetenskapliga underlaget som låg (GRADE ⊕⊕◯◯). För utfallen prolapssymtom, långvarig smärta, samlagssmärta och vårdtid är det osäkert huruvida det föreligger några skillnader mellan behandlingarna (mycket låg tillförlitlighet, GRADE ⊕◯◯◯). Varken sjukskrivningstid eller patientrapporterad tolerans för fysisk belastning har jämförts i studier av dessa två metoder.
Sakrospinosusfixation vs Manchesteroperation
En icke-randomiserad kontrollerad studie rapporterade högre förekomst av reoperationer efter sakrospinosusfixation jämfört med Manchesteroperation. Tillförlitligheten för dessa resultat bedöms som låg (GRADE ⊕⊕◯◯). För de övriga utfallen saknas studier som jämför dessa två metoder.
Titthålskirurgi vs Manchesteroperation Inga studier som jämför dessa metoder har rapporterats.

Kostnader
Enligt en databas av patientkostnader i VGR år 2019 och 2020 var den genomsnittliga kostnaden per patient som erhöll sakrospinosusfixation 66 500 SEK, för framfallsoperation via titthål 117 800 SEK och för Manchesteroperation 43 300 SEK.

Etiska aspekter
Baserat på fynden (begränsat vetenskapligt underlag, små eller inga skillnader avseende viktiga utfallsmått, en möjligen kortare operationstid samt lägre kostnad för sakrospinosusfixation), är en viktig etisk aspekt huruvida den laparoskopiska metoden skall erbjudas annat än i forskningssammanhang.

Slutsatser Det vetenskapliga underlaget för att jämföra sakrospinosusfixation med titthålskirurgi är begränsat. Avseende hälsorelaterad livskvalitet, patientnöjdhet, reoperation, återfall och urininkontinens kan det finnas ingen eller en liten skillnad mellan metoderna. Operationstiden kan vara kortare och besvär från urinvägarna något färre vid sakrospinosusfixation.
Enbart en icke-randomiserad kontrollerad studie har jämfört sakrospinosusfixation med Manchesteroperationen och resultaten tyder på att re-operationer kan vara färre efter Manchesteroperation. Det saknas underlag för att utvärdera vård- och sjukskrivningstid, samt patientrapporterad tolerans för fysisk belastning. För jämförelsen av laparoskopisk kirurgi med Manchesteroperationen saknas vetenskapliga studier.

The above summaries were written by representatives from the HTA-centrum. The HTA report was approved by the regional board for quality assurance of activity-based HTA. The abstract is a concise summary of the results of the systematic review. The Swedish summary is a brief summary of the systematic review intended for decisionmakers.

Christina Bergh, Professor, MD
Head of HTA-centrum of Region Västra Götaland, Sweden, November 24th 2021.

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DDS Doctor of dental surgery
MD Medical doctor
PhD Doctor of Philosophy
OD Odontology doctor
PT Physiotherapist
RN Registered Nurse

3. Summary of findings

Outcomes	Study design (Number of patients)	Absolute effect	Certainty of evidence GRADE[1]
Sacrospinous fixation (SSF) vs laparoscopic sacrocolpopexy/sacrohysteropexy (LSC/LSH)			
HRQL[7]	1 RCT (126) 1 cohort study (208)	No sign. difference in any of the SF36 dimensions UDI: SSF sign. lower median score in 1/5 dimensions (overactive bladder) No sign. difference in PFDI-20, or UDI-6 scores	⊕⊕◯◯[1] Little or no difference
Awareness of prolapse	1 RCT (126) 1 cohort study (111)	Awareness of prolapse post-surgery: RCT: SSF: 0, LSC/LSH: 0 Non-RCT: SSF: 12%, LSC/LSH: 22% n.s.	⊕◯◯◯[2]
Patient satisfaction	1 RCT (126) 1 cohort study (111)	RCT: SSF:90%, LSC/LSH:86% n.s. Non-RCT: SSF:82%, LSC/LSH:78% n.s.	⊕⊕◯◯[1] Little or no difference
Reoperation	1 RCT (126) 1 cohort study (111)	Any compartment RCT: SSF: 5%, LSC/LSH: 3%, difference 2% (95% CI -5% to 9%) Non-RCT: SSF: 4%, LSC/LSH: 20%, p:0.015 Apical compartment RCT: SSF: 3%, LSC/LSH: 0, difference 3% (95% CI -1% to 8%)	⊕⊕◯◯[1] Little or no difference
Recurrent prolapse	1 RCT (126) 2 cohort studies cohort study A (208) cohort study B (111)	RCT: SSF: 3% LSC/LSH: 2%, difference: -2% (95% CI -4% to 8%) Cohort study A: SSF: 5%, LSC/LSH: 4%, n.s. Cohort study B: SSF: 0, LSC/LSH:0, yet 12% with early reoperation due to failure of technique)	⊕⊕◯◯[1] Little or no difference
Dyspareunia	1 RCT (76) 1 cohort study (52)	RCT: De novo dyspareunia: SSF: 13% LSC/LSH:8% n.s. Non-RCT: Dyspareunia post-OP: SSF: 25%, LSC/LSH 28% n.s.	⊕◯◯◯[2]
Chronic pain	1 cohort study (208)	SSF: 8% with pain mainly relieved within 6 weeks LSC/LSH: 12% with pain gradually diminished after 6 months	⊕◯◯◯[3]
Urinary incontinence (including de novo)	1 RCT (126), 1 cohort study (208)	RCT: UDI-scores at post-op median (interquartile range) Urinary incontinence: SSF: 0 (0-17), LSC/LSH: 17 (0-33) n. s. Overactive bladder: SSF:0 (0-11), LSC/LSH 11 (0-22) p=0.012 Non-RCT: De novo urinary incontinence SSF:11%, LSC/LSH:24%, n.s	⊕⊕◯◯[1] Little or no difference
Operative time (minutes)	3 cohort studies cohort study A (208) cohort study B (90) cohort study C (101)	Operative time, mean (SD) Cohort study A: SSF: 120 (31) LSC/LSH 158 (72), p≤0.001 Cohort study B: SSF: 160 (56), LSH: 285 (77), RASH: 345 (60) p≤0.001 for all three comparisons Operative time, median (range) Cohort study C: SSF: 62 (30 to 137), LSC/LSH; 129 (45 to 235), p≤0.001	⊕⊕◯◯[4] Favors SSF
Duration of hospital stay (days)	2 non-RCT Cohort study A (208) Cohort study B (111)	Days in hospital Cohort study A: mean (SD) SSF: 11 (3) LSC/LSH: 8 (3) p<0.001 Cohort study B: median (range) SSF: 4 (1 to 18) LSC/LSH: 4 (2 to 21)	⊕◯◯◯[5]
No data on patient-reported tolerance of physical load, or duration of sick leave			
Sacrospinous fixation vs Manchester-procedure			
		Relative effect	
Reoperation	1 cohort study (3202)	Any compartment: SSF: 21% Manchester: 6%, aHR 5 (95% CI 4 to 7) Apical compartment SSF: 13% Manchester: 0.5%, aHR 40 (95% CI 22 to 75)	⊕⊕◯◯[6] Favors Manchester
None of the other outcomes have been studied in controlled trials.			
Laparoscopic sacrocolpopexy/sacrohysteropexy vs Manchester procedure			
No controlled studies available			
Complications			
Urinary tract complications observed after all three interventions. In addition, pelvic, thigh or gluteal pain after **SSF.** Venous thromboembolic complications (up to 0,4%), and surgical site infections (up to 1,4%) after **LSC/LSH**.			

SF36: 36-item short form survey, scores from 0 – 100 with higher values indicating better quality of life, UDI: Urogenital Distress Inventory, scores from 0 – 100 with higher scores indicating worse symptoms, PFDI: pelvic floor distress inventory scores from 0 – 80 with higher scores indicating worse function, n.s: not significant, aHR: adjusted hazard ratio

[1] Downgraded for some study limitations, some indirectness and serious imprecision
[2] Downgraded for some study limitations, some indirectness and very serious imprecision
[3] Starting from ++ for cohort studies, downgraded for serious study limitations, and imprecision and some indirectness
[4] Starting from ++ for cohort studies, downgraded for some study limitations, some indirectness and some imprecision, upgraded for large effect.
[5] Starting from ++ for cohort studies, downgraded for some study limitations and imprecision and serious indirectness [6] Starting from ++ for cohort studies, not downgraded for study limitations, indirectness, or imprecision.
[7] For detailed results regarding HRQL see Appendix 4.1

Certainty of evidence

High certainty ⊕⊕⊕⊕	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty ⊕⊕⊕◯	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty ⊕⊕◯◯	Confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low certainty ⊕◯◯◯	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

4. Abbreviations/Acronyms

HRQL	Health-related Quality of Life
LSC	Laparoscopic sacrocolpopexy; in this report including both traditional laparoscopic techniques and robot assisted techniques RASC
LSH	Laparoscopic sacrohysteropexy; in this report including both traditional laparoscopic techniques and robot assisted techniques RASH
PFDI-20	Pelvic floor distress inventory
POP	Pelvic organ prolapse
RASC	Robotic assisted sacrocolpopexy
RASH	Robotic assisted sacrohysteropexy
RCT	Randomised controlled trial
SF-36	36-item short form survey
SSF	Sacrospinous fixation: including both SSLF and SSHP
SSLF	Sacrospinous ligament fixation (with previous or concomitant hysterectomy)
SSHP	Sacrospinous hysteropexy (uterus-preserving technique)
UDI	Urogenital distress inventory

5. Background

Disease/disorder of interest and its degree of severity

Pelvic organ prolapse (POP) can be defined as the descent of one or more of the anterior vaginal wall, posterior vaginal wall, the uterus (cervix) or the apex of the vagina (vaginal vault after hysterectomy). This definition is anatomic and some of the changes described may be asymptomatic for many women. If symptoms occur, these include vaginal bulging, pelvic pressure/heaviness, voiding dysfunction, defecatory dysfunction, sometimes a need of digitation or splinting referring to the need of manually replacing the prolapse to assist voiding or defecation. There are also symptoms related to sexual dysfunction such as dyspareunia, obstructed intercourse, vaginal laxity, and decreased libido (Haylen et al., 2016). Prolapse is often divided into different vaginal compartments; anterior, posterior or apical, depending on where the anatomical weakness is situated. This report evaluates surgical treatment for apical prolapse, i.e. the descent of the uterus, cervix or vaginal vault.

Degree of severity

Symptomatic POP affects women's emotional health and well-being (Ghetti et al., 2015). For the majority of patients undergoing treatment for POP, the treatment is offered to improve quality of life (Mattsson et al., 2020). However, there is a correlation between severe POP and hydronephrosis and there have been cases of renal failure with risk of permanent damage due to pronounced POP. A systematic review identified a prevalence of hydronephrosis ranging from 3.5% to 30.6% among women with POP and there was a correlation with severity of prolapse (Siddique et al., 2020, Miyagi et al., 2017).

Prevalence and incidence

The prevalence of POP differs a lot between studies. POP with subjective symptoms shows a lower prevalence than POP diagnosed by vaginal examination (Sung and Hampton, 2009). A study based on vaginal examination shows a prevalence of 41.1% among women 50-79 years (Hendrix et al., 2002) while a study based on symptoms shows a prevalence of 5.7% among women 40-69 years (Rortveit et al., 2007). Among Swedish women 30-79 years old a prevalence of 8.3% for symptomatic POP was found (Tegerstedt et al., 2005). Studies have shown a lifetime risk of having a POP surgery of around 10% (Kurkijärvi et al., 2017, Abdel-Fattah et al., 2011). In 2019, 6181 prolapse surgeries were registered in the national quality register of gynecological surgery (GynOp), out of these 1751 included surgery for apical prolapse (Bergman, 2019).

Present treatment

Conservative treatment includes lifestyle interventions such as weight loss and avoiding heavy lifting aiming to reduce intra-abdominal pressure. Chronic cough should be assessed and, if possible, treated. Pelvic floor muscle training has been shown to reduce symptoms. Vaginal pessaries can be offered as support and treatment (Haylen et al., 2016, Basnet, 2021). However, many patients with POP will benefit from surgical intervention.

When surgery is indicated the aim is to build a reliable support to reduce the prolapse and hence the symptoms. If an apical prolapse is present, there are two different categories of surgeries: obliterative or reconstructive. The obliterative surgery, colpocleisis, is synonymous with a closure of the vagina and can be performed with or without a hysterectomy. This procedure has high patient satisfaction and anatomic success (Meriwether et al., 2020). However, it is suitable only for a small number of patients, often elderly, who have no wish to keep a functional vagina. A reconstructive approach is more appealing for most patients and when it comes to building up support for apical prolapse, various surgical techniques are in practice. They all aim to suspend the apex of the vagina or the uterus/cervix to different ligaments above the pelvic floor.

It is recognised that a hysterectomy alone is not a sufficient POP-surgery. Some sort of surgical intervention for apical support is essential (Meriwether et al., 2020).

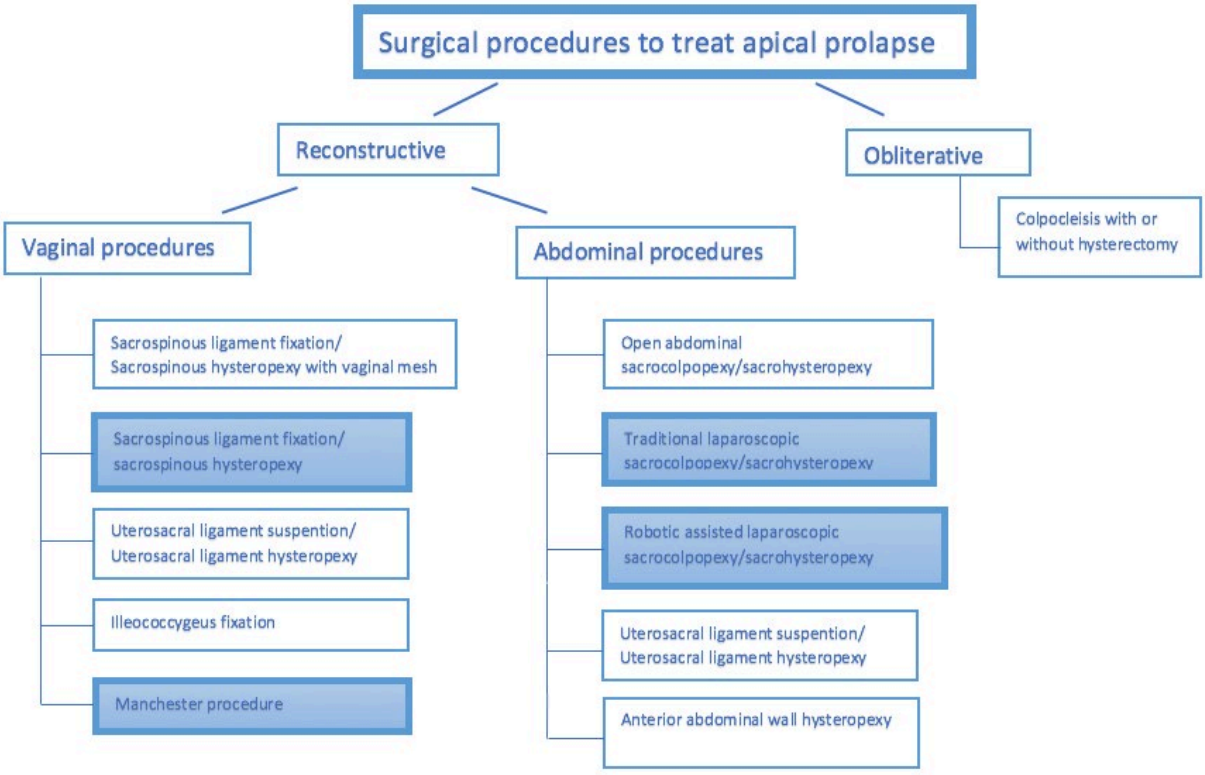

Figure 1: Different surgical methods to treat apical prolapse – the methods compared in this report are highlighted in the figure. Adapted from (Meriwether et al., 2020)

There is no convincing evidence when to recommend uterine-preservation surgery and when to recommend hysterectomy as a part of POP-surgery (Maher et al., 2016). However, a study evaluating trends in POP-surgery in Denmark concludes that uterine preserving techniques are increasing and in 2016, 90% of surgeries performed to treat apical prolapse were uterine-preserving (Husby et al., 2020). Studies have shown that women prefer to retain their uterus if the outcome of the uterine-preservation technique is equal to the technique involving hysterectomy (Frick et al., 2013, van IJsselmuiden et al., 2018).

At Sahlgrenska University Hospital, several different reconstructive surgical methods to treat apical prolapse are used, the most common being SSF followed by the Manchester procedure and LSC/LSH. In Sweden, the most used method is the Manchester procedure, followed by vaginal hysterectomy, SSF and then LSC/LSH. The practice differs considerably between different gynecological clinics in Sweden (Bergman, 2019). The Manchester procedure is an old procedure, first described in 1888. A Manchester-Fothergill procedure traditionally includes cervix amputation, ligament suspension and anterior and posterior colporhaphy. A review concludes that many younger gynecologists are not familiar with the Manchester procedure but highlights that the procedure has many advantages and has proven to be safe and effective for more than a century (Marquini et al., 2022).

A Cochrane review from 2016 suggests that sacrocolpopexy is associated with less reoperations and lower risk of awareness of prolapse at follow-up than vaginal procedures. That review included studies with a minimum of 6 months follow-up and the majority of publications included had a follow-up of less than one year. (Maher et al., 2016).

A systematic review and guideline published 2021 by the society of obstetricians and gynecologists of Canada concludes that sacrocolpopexy has a lower rate of objective failure than vaginal suspension techniques (Geoffrion et al., 2021). These results are difficult to interpret as both reviews compare sacrocolpopexy- both open and laparoscopic - with a variety of different vaginal surgical methods. Therefore, it remains unclear if any of the vaginal methods is more effective than the others. Also, studies included in the Cochrane review relate primarily to patients with vault prolapse post-hysterectomy.

The normal pathway through the healthcare system and current wait time for medical assessment/treatment

The initial diagnosis and management of POP is usually done at a primary health care center or at a gynecologist practice. If the patient is interested in surgical treatment, she is referred to a hospital with urogynecology expertise. Wait time from decision for surgery until operation is commonly around 1 year.

Number of patients per year who undergo current treatment regimen

At Sahlgrenska University Hospital, 63 patients underwent SSF, 27 patients underwent the Manchester procedure, and 13 patients underwent LSC/LSH, during 2019.

Present recommendations from medical societies or health authorities

There are no national guidelines for which surgical method to recommend for the management of apical prolapse. The Swedish association for obstetrics and gynecology (Svensk Förening för Obstetrik och Gynekologi, SFOG) is currently working on national recommendations for the treatment of apical prolapse.

6. Sacrospinous fixation (SSF); laparoscopic sacrocolpopexy/sacrohysteropexy (LSC/LSH) and the Manchester procedure

The following three reconstructive surgical methods to treat apical prolapse are compared

Sacrospinous fixation (SSF): The SSF is most commonly a vaginal procedure. After a vaginal incision and dissection, the sacrospinous ligament is identified. This is usually done at the right side, to minimize the risk of rectal perforation. Sutures are then placed in the sacrospinous ligament and attached to the apex of the vagina. If the uterus is still present, a concurrent hysterectomy can be performed, or the uterus can be spared and the sutures are then attached to the cervix. It is suggested that the surgery for vault prolapse or with a concurrent hysterectomy is called Sacrospinous ligament fixation (SSLF) and with a uterine preserving approach is called Sacrospinous hysteropexy (SSHP) (Meriwether et al., 2020).

There are various surgical techniques involving transvaginal mesh application. However, in 2011 the FDA raised serious safety and effectiveness concerns regarding transvaginal mesh surgery (ACOG, 2019). The reported severe adverse events included mesh erosion, pain, dyspareunia, vaginal bleeding, infections and organ perforation. No distinct improvement of clinical benefits were seen after mesh surgery compared with traditional non-mesh methods (FDA, 2011). Since 2019 FDA ordered manufacturers to stop selling transvaginal mesh products in the US (ACOG, 2019). Transvaginal mesh surgery is still performed at Sahlgrenska University Hospital, yet this method is limited to rare cases and never as a first line treatment. Hence, surgical techniques involving transvaginal mesh are excluded in this report.

Laparoscopic sacrocolpopexy/sacrohysteropexy: Sacrohysteropexy or sacrocolpopexy refers to the attachment of either uterus or vagina (in case of previous or concomitant hysterectomy) to the anterior longitudinal ligament of sacrum using a graft. First the abdominal cavity is entered, which can be done either open with laparotomy or with minimally invasive techniques - traditional laparoscopic technique or robotic assisted. The cervix and vaginal walls and the presacral space at the promontorium are dissected. If a sacrohysteropexy is performed, the graft is attached to the cervix and/or isthmus and in some cases also to the fibromuscular layer of the vagina. If a sacrocolpopexy is performed, the graft is attached to the posterior and anterior wall of the vagina. After that, the graft is attached to the anterior longitudinal ligament of the sacrum. Laparoscopic surgery has been shown to be associated with less complications and a shorter time to return to normal activity compared with open surgery (Medeiros et al., 2009; Jaschinski et al., 2018). A systematic review and meta-analysis conclude that minimally invasive sacrocolpopexy and open abdominal sacrocolpopexy show no difference in effectiveness of treating POP, however there is a higher risk for perioperative complications and longer length of hospital stay with an open approach (De Gouveia et al., 2016). Therefore, only laparoscopic techniques, both traditional and robotic assisted, are included in this HTA-report.

Manchester procedure: The Manchester procedure is a vaginal procedure which includes an amputation of the cervix. The uterosacral ligaments are identified bilaterally and then plicated across the midline. Finally, the vaginal mucous membrane is closed.

The aim of comparing these three surgical methods is to provide the most effective surgery with the least complications for women receiving surgical treatment of apical prolapse. Studies indicate that sacrocolpopexy/hysteropexy have a better outcome than vaginal procedures. However, no review of the literature comparing sacrocolpopexy/hysteropexy to the most common surgical methods used at Sahlgrenska University Hospital and at Swedish gynecological clinics exists.

Another aim is to make a cost-effectiveness analysis between the different surgical methods and to evaluate what impact an eventually higher proportion of laparoscopic procedures would have on costs and waiting times for surgical treatment.

7. Focused question

How do Laparoscopic sacrocolpopexy/sacrohysteropexy, sacrospinous fixation and the Manchester procedure compare, when it comes to effectiveness in treating apical prolapse, risk for adverse events and regarding costs for surgery?

	PICO
P	Women receiving surgical treatment of apical prolapse
I	I1: **Sacrospinous fixation (SSF):** including both sacrospinous ligament fixation (SSLF) and sacrospinous hysteropexy (SSHP) (excluding procedures with vaginal mesh) I2: **Laparoscopic sacrocolpopexy/sacrohysteropexy (LSC/LSH):** including traditional laparoscopic technique, robotic assisted laparoscopic technique (robotic assisted sacrocolpopexy (RASC), and robotic assisted sacrohysteropexy (RASH)) I3: **Manchester procedure**
C	C1: **Sacrospinous fixation (SSF):** as in I1 above C2: **Laparoscopic sacrocolpopexy/sacrohysteropexy (LSC/LSH):** as in I2 above C3: **Manchester procedure**
O	<u>Critical for decision making</u> HRQL (preferably validated scales) Awareness of prolapse (subjective bulging symptoms/feeling of heaviness) Patient satisfaction Reoperation (any or same compartment) Recurrent prolapse (apical compartment) <u>Complications</u> <u>Important for decision making</u> Dyspareunia Chronic pain Patient-reported tolerance of physical load (lift, carry, run, exercise) Urinary incontinence (including de novo) <u>Other outcomes of interest</u> Operative time Duration of hospital stay Duration of sick leave

The relevance of the included outcomes was confirmed by a patient organization representative who participated in defining the focused question of this review.

6. Methods

Systematic literature search (Appendix 1)

During April 2021 two authors (TS, IS) performed systematic searches in PubMed, Embase, the Cochrane Library, Cinahl, Amed, PsycInfo and a number of HTA-databases. Reference lists of relevant articles were also scrutinized for additional references. Search strategies, eligibility criteria and a graphic presentation of the selection process are presented in Appendix 1. These authors conducted the literature searches, selected studies, and independently of one another assessed the obtained abstracts and made a first selection of full-text articles for inclusion or exclusion. Any disagreements were resolved in consensus. The remaining articles were sent to all the participants of the project group. All authors read the articles independently of one another and it was finally decided in a consensus meeting which articles should be included in the assessment.
The review was registered in PROSPERO (registration ID: CRD42021255685) prior to data extraction.

Critical appraisal and certainty of evidence

The included studies and their design as well as patient characteristics are presented in Appendix 2. Data were extracted and controlled by at least two authors.

Included studies were critically appraised using the checklists for assessment of randomised controlled trials (RCT) and non-randomised controlled trials provided by the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU). For the assessments of directness and precision, a modified checklist from a prior version of the SBU checklist was used. In Appendices 4.1 to 4.12 the results and the quality of each study are summarised per outcome. Results per outcome and the associated certainty of evidence are presented in a Summary-of-findings table (page 9). The certainty of evidence was assessed according to GRADE (Atkins et al., 2004), with reasons for downgrading described in text.

Ongoing research

A search in Clinicaltrials.gov (2021-08-20) using the search terms *((prolapse OR prolapses OR POP OR procidentia) AND (sacrospinous OR sacro-spinous OR sacrospinal OR sacro-spinal OR sacrospinofixation OR sacrospinofixations OR colpopexy OR colpopexies OR sacrocolpopexy OR sacrocolpopexies OR colposacropexy OR colposacropexies OR perineopexy OR perineopexies OR colpoperineopexy OR colpoperineopexies OR sacrocolpoperineopexy OR sacrocolpoperineopexies OR hysteropexy OR hysteropexies OR sacrohysteropexy OR sacrohysteropexies OR hysterosacropexy OR hysterosacropexies OR uteropexy OR uteropexies OR sacrouteropexy OR sacrouteropexies OR uterosacropexy OR uterosacropexies OR vaginopexy OR vaginopexies OR sacrovaginopexy OR sacrovaginopexies OR vaginosacropexy OR vaginosacropexies OR cervicopexy OR cervicopexies OR sacrocervicopexy OR sacrocervicopexies OR cervicosacropexy OR cervicosacropexies OR sacropexy OR sacropexies OR Manchester))* identified 176 trials. A search in WHO ICTRP (2021-08-20) using the search terms *((prolapse OR POP OR procidentia) AND (sacrospin* OR sacro-spin* OR colpopex* OR sacrocolpopex* OR colposacropex* OR perineopex* OR colpoperineopex* OR sacrocolpoperineopex* OR hysteropex* OR sacrohysteropex* OR hysterosacropex* OR uteropex* OR sacrouteropex* OR uterosacropex* OR vaginopex* OR sacrovaginopex* OR vaginosacropex* OR cervicopex* OR sacrocervicopex* OR cervicosacropex* OR sacropex* OR Manchester*))* identified 189 trials. In total 246 unique ongoing trials were identified.

7. Results

Search results and study selection (Appendix 1)

The literature search identified 2,244 articles after removal of duplicates. After reading the abstracts 1,999 articles were excluded. Another 135 articles were excluded by two authors after reading the articles in full text. The remaining 110 articles were sent to all participants of the project group, and 38 articles (one RCT, six cohort studies and 31 case series) were finally included in the assessment (Appendix 2).

Included studies

38 studies were included. One RCT from the Netherlands including 126 patients comparing SSF with LSC/LSH (van IJssemuiden et al., 2020). Five cohort studies compared SSF with LSC/LSH. Together these cohort studies included 28,931 patients, three studies were from the USA, one from China and one from Sweden (Bruseke et al., 2020, Chen et al., 2017, Kow et al., 2016, Lua et al., 2017, Marcickiewiz et al., 2007). One cohort study from Denmark included 3202 patients comparing SSF with the Manchester procedure (Husby et al., 2019). The time of follow-up in the cohort studies varies between studies reporting on perioperative outcomes only and up to 3.5 years. No studies comparing LSC/LSH with the Manchester procedure were identified. 31 studies were included as case series to evaluate complications for one of the surgical methods, and of these studies 13 dealt with SSF, 14 with LSC/LSH and 4 with the Manchester procedure.

The RCT included patients without previous hysterectomy and no concomitant hysterectomy was performed in the SSF or the LSC/LSH group. Four of the cohort studies comparing SSF and LSC/LSH included patients with or without previous hysterectomy, and hysterectomy was performed as concomitant treatment in different proportions in these studies. The fifth cohort study (Marcickiewiz et al., 2007) only included patients with previous hysterectomy. In two of the cohort studies (Bruseke et al., 2020, Kow et al., 2016) results regarding robot assisted laparoscopic surgery are presented.
The cohort study comparing SSF and the Manchester procedure excluded patients with previous hysterectomy and no data on concomitant hysterectomy was available.

The RCT was considered to have some problems with directness due to only dealing with a subgroup of the population of interest, women with uterus still in place. In addition, the RCT did not provide any information on exclusions prior to randomisation. A skewed drop-out rate was noted as a study limitation in the RCT. Overall, the cohort studies comparing SSF and LSC/LSH were considered to have minor problems with directness, for the different outcomes some or serious problems with precision, and major problems with study limitations, mostly because of poor description of baseline characteristics or not adjusting for differences in baseline characteristics. The cohort study comparing SSF and the Manchester procedure was considered to have no or minor problems regarding study limitations, directness and precision.

Results regarding sacrospinous fixation vs laparoscopic sacrocolpopexy/sacrohysteropexy per outcome

Outcomes critical for decision-making

Health-related quality of life (Appendix 4.1)

The RCT (van IJssemuiden et al., 2020) and one cohort study (Chen et al., 2017) reported data on HRQL. In the RCT HRQL was measured with SF-36 (36-item short form survey). Participants also answered UDI (urogenital distress inventory), DDI (defecatory distress inventory), incontinence impact questionnaire, and PISQ-12 (Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire).

HRQL was assessed pre-OP and post-OP. Between-group comparisons were based on post-OP results, thus not considering some imbalances regarding HRQL between patient groups before surgery. In the non-RCT, HRQL was measured with PFDI-20 (pelvic floor distress inventory). Participants also answered POPDI-6 (Pelvic Organ Prolapse Distress Inventory 6), CRADI-8 (Colorectal-Anal Distress Inventory 8) and UDI-6 (Urinary Distress Inventory 6). In both studies and for both surgical methods HRQL was improved postoperatively. In both studies there were no statistically significant differences in overall HRQL between the surgical methods. (For detailed results see Appendix 4.1). However, in the RCT, more symptoms of overactive bladder and fecal incontinence were reported after LSC/LSH. In UDI (scale from 0-100), the post-OP median score (interquartile range) regarding overactive bladder was 0 (0-11) in the SSF group reflecting slightly less bothersome symptoms compared with 11(0-22) in the LSC/LSH group (p=0.012). In the DDI the post-OP median (interquartile range) in the SSF group was 0 (0-0) reflecting slightly less bothersome symptoms of fecal incontinence compared with 0 (0-17) in the LSH group. In addition, the RCT reports persistent fecal incontinence in 3 % (2/58) in the SSF group compared to 10 % (6/59) in the LSC/LSH group. In the non-RCT, UDI-6 and CRADI-8 scores were improved post-OP with statistical significance in the SSF group only.

Conclusion: When SSF is compared with LSC/LSH there may be little or no difference in overall HRQL. However, SSF may result in slightly better results regarding urogenital distress symptoms (low certainty of evidence: GRADE ⊕⊕◯◯).

Awareness of prolapse (Appendix 4.2)
The RCT (van IJssemuiden et al., 2020) and one cohort study (Marcickiewiz et al., 2007) reported on awareness of prolapse. Time of follow up in the RCT was 12 months and in the cohort study over 24 months. In the RCT no patients reported on awareness of prolapse at follow up. The observation of zero events limits the precision of evaluating this outcome. In the cohort study 11.8% in the SSF group and 21.7 % in the LSC/LSH group reported awareness of prolapse at follow up. There was no statistically significant difference in awareness of prolapse in any of the studies.

Conclusion: It is uncertain whether there is a difference between treatment with SSF compared to LSC/LSH regarding awareness of prolapse in women receiving surgical treatment of apical prolapse (very low certainty of evidence: GRADE ⊕◯◯◯).

Patient satisfaction (Appendix 4.3)
The RCT (van IJssemuiden et al., 2020) and one cohort study (Marcickiewiz et al., 2007) reported on patient satisfaction. Length of follow-up was 12 and over 24 months, respectively. In the RCT 89.7% in the SSF group and 86.2% in the LSC/LSH group were satisfied with the results and procedure. In the cohort study 82% in the SSF group and 78% in the LSC/LSH group were satisfied with the results and procedure. These differences were not statistically significant.

Conclusion: For women receiving surgical treatment of apical prolapse, there may be little or no difference between treatment with SSF compared with LSC/LSH regarding patient satisfaction (low certainty of evidence: GRADE ⊕⊕◯◯).

Reoperation (Appendix 4.4)
The RCT (van IJssemuiden et al., 2020) and one cohort study (Marcickiewiz et al., 2007) report data regarding reoperation. At 12 months follow up in the RCT, reoperation in apical compartment was performed in 3% of patients in the SSF group compared to none in the LSC/LSH group; reoperation in any compartment was reported for 5% in the SSF group and 3% in the LSC/LSH group. There was no statistically significant difference in reoperation in either apical or any compartment.
The cohort study was considered to have serious study limitations amongst others due to differences between treatment groups at baseline that were not considered in the analysis.

This study reported more reoperations in any compartment in the LSC/LSH group (20%) than in the SSF group (4%), with a statistically significant difference. In the discussion the authors argue that the reoperations in apical compartment (12%, n=7) in the LSC/LSH group were all early reoperations at the start of the study period due to failure of technique, the technique was later altered during the study period.

Conclusion: For women receiving surgical treatment of apical prolapse, there may be little or no difference between treatment with sacrospinous fixation compared with laparoscopic sacrocolpopexy/sacrohysteropexy regarding the need for reoperations
(low certainty of evidence: GRADE ⊕⊕◯◯).

Recurrent prolapse (Appendix 4.5)
The RCT (van IJssemuiden et al., 2020) and two cohort studies (Chen et al., 2017; Marcickiewiz et al., 2007) reported on recurrent prolapse. In the RCT a composite outcome defined as recurrent apical prolapse ≥ POP-Q stage 2 and bothersome protrusion/bulging symptoms and/or requiring therapy (surgery or pessary) was studied. Recurrence was reported in 3.4% in the SSF group and in 1.9% in the LSC/LSH group. There was no statistically significant difference between the different surgical methods (difference 2%, 95% CI: -4.3% to 7.5%). One of the cohort studies reported recurrence in 5% of patients treated with SSF and in 4% of those treated with LSC/LSH, with no statistically significant difference between the different surgical methods. The other cohort study showed an initial failure where seven patients (12%) in the LSC/LSH group had a reoperation shortly after the initial operation. In the discussion the authors argue that this was due to failure of technique and the technique was later altered. No patient in the SSF group had an initial failure. This was a statistically significant difference. However, at the follow up visit after the initial operation and for some patients after early reoperation with altered technique, there was no recurrence of prolapse in any of the groups.

Conclusion: For women receiving surgical treatment of apical prolapse, there may be little or no difference between treatment with sacrospinous fixation compared with laparoscopic sacrocolpopexy/sacrohysteropexy in recurrence of prolapse
(low certainty of evidence: GRADE ⊕⊕◯◯).

Complications in comparative studies of sacrospinous fixation vs laparoscopic sacrocolpopexy/sacrohysteropexy (Appendix 4.11a)

Three cohort studies comparing SSF with LSC/LSH reported comparisons of complications that were not defined as specific outcomes critical or important for decision- making in this report. Complications analyzed were postoperative blood transfusions, perioperative estimated blood loss and readmission within 90 days. In the study comparing the rate of readmission, results in the SSF group were 4.22% (95% CI 3.93-4.53) compared to 4.64% (95% CI 4.26-5.06) in the LSC/LSH group. In the study evaluating post-operative blood-transfusion, 1.7% (1 patient) in the SSF group and 0.5% (1 patient) in the LSC/LSH group received post-OP blood transfusion. In the study reporting data on blood loss the mean (SD) estimated blood loss in the SSF group was 89 ml (100 ml) compared to 136 ml (102 ml) in the traditional laparoscopic LSH group, and 113 ml (78 ml) in the robotic assisted LSH group.

Outcomes important for descision-making

Dyspareunia (Appendix 4.6)
The RCT (van IJssemuiden et al., 2020) and one cohort study (Marcickiewiz et al., 2007) reported on dyspareunia. In the RCT only a subgroup of sexually active women (about 60% of included patients) answered the questions about sexual function. De novo dyspareunia was reported for 13% in the SSF group compared with 8% in the LSC/LSH group, with no statistically significant difference between the different surgical methods.

In the cohort study 25% in the SSF group and 28.1% in the LSC/LSH group experienced dyspareunia post surgery, related information on dyspareunia pre-surgery is not provided. The comparison of post-surgery results was not statistically significant.

Conclusion: It is uncertain whether there is a difference between treatment with SSF compared to LSC/LSH regarding dyspareunia in women receiving surgical treatment of apical prolapse (very low certainty of evidence: GRADE ⊕◯◯◯).

Chronic pain (Appendix 4.7)
One cohort study (Chen et al., 2017) reported on pain. In the SSF group 8.4% complained of pain which was mainly relieved within 6 weeks. In the LSC/LSH group 11.5% complained of pain which diminished gradually after 6 months. It can be noted that the definition of chronic post-surgical pain in ICD-11 (International Classification of Diseases-11) is defined as pain lasting more than 3 months after surgery (Treede et al., 2019).

Conclusion: It is uncertain whether there is a difference between treatment with SSF compared with LSC/LSH regarding the occurrence of chronic pain in women receiving surgical treatment of apical prolapse (very low certainty of evidence: GRADE ⊕◯◯◯).

Patient-reported tolerance of physical load
No studies.

Urinary incontinence (including de novo) (Appendix 4.8)
The RCT (van IJssemuiden et al., 2020) and one cohort study (Chen et al., 2017) reported on urinary incontinence. In the RCT patients responded to the urogenital distress inventory-6 before and after surgery. The scale ranges from 0 = no symptoms to 100= most bothersome symptoms. When evaluating urinary incontinence median values before and after surgery were 17 and 0 in the SSF group, while the corresponding values were 25 and 17 in the LSC/LSH group (no significant difference between groups post-OP). When evaluating symptoms of overactive bladder in the SSF group the median value was 22 pre-OP and 0 post-OP. In the LSC/LSH group the median value was 22 pre-OP and 11 post-OP. This was statistically significant (p=0.012) between groups post-OP. Two patients in the LSC/LSH group reported de novo overactive bladder symptoms whereas no de novo overactive bladder symptoms were reported in the SSF group. In the cohort study 11.4% in the SSF group and 23.8% in the LSC/LSH group reported de novo stress urinary incontinence. The difference was not statistically significant.

Conclusion: For women receiving surgical treatment of apical prolapse, there may be little or no difference between treatment with sacrospinous fixation compared with laparoscopic sacrocolpopexy/sacrohysteropexy regarding urinary incontinence (low certainty of evidence: GRADE ⊕⊕◯◯).

Other outcomes of interest

Operative time (Appendix 4.9)
Three cohort studies (Chen et al., 2017, Kow et al., 2016; Marcickiewiz et al., 2007) reported on operative time. The studies had serious study limitations as e.g. imbalances in baseline characteristics not corrected for and a lack of information on concomitant procedures which may affect the operative time. In all three studies SSF had a considerably shorter operative time. The difference of mean or median operative time ranged from 38 minutes to 185 minutes. Mean (SD) operative times in the first study were 120 (31) minutes in SSF compared to 158 (72) minutes for LSH/LSC, a statistically significant difference. In the second study measuring the total operating room time, the mean duration was 160 (56) minutes for SSF compared to 285 (77) minutes for LSH and 345 (60) minutes for robot

assisted sacrohysteropexy. The third study reported median (range) duration from incision to last suture of 62 (30 – 137) minutes for SSF and 129 (45 – 235) minutes for LSC/LSH. All three comparisons between the three surgical methods were statistically significant.

Conclusion: For women receiving surgical treatment of apical prolapse, treatment with SSF compared with LSC/LSH may imply a shorter operative time, yet based on available studies,'
the magnitude of difference is uncertain (low certainty of evidence: GRADE ⊕⊕◯◯).

Length of hospital stay (Appendix 4.10)
Two cohort studies (Chen et al., 2017; Marcickiewiz et al., 2007) reported on length of hospital stay. One of the cohort studies showed a statistically significant longer length of hospital stay for women in the SSF group. The other cohort study reported on slightly longer length of hospital stay for women in the LSC/LSH group. The hospital stay ranged from 3.7 days to 10.6 days.
In the Swedish context these operations are performed as outpatient surgery or maximum with one-night stay at hospital, hence the directness and transferability of these data to the Swedish context is considered low regarding this outcome.

Conclusion: It is uncertain whether there is a difference between treatment with sacrospinous fixation compared to laparoscopic sacrocolpopexy/sacrohysteropexy regarding the length of hospital stay for women receiving surgical treatment of apical prolapse
(very low certainty of evidence: GRADE ⊕◯◯◯).

Duration of sick leave
No studies reporting on duration of sick leave were identified.

Results regarding sacrospinous fixation vs Manchester procedure per outcome

Outcomes critical for decision-making

Health-related quality of life (Appendix 4.1)
No studies.

Awareness of prolapse (Appendix 4.2)
No studies.

Patient satisfaction (Appendix 4.3)
No studies.

Reoperation (Appendix 4.4)
One cohort study (Husby et al., 2019) reported on reoperation comparing SSF with the Manchester procedure. Reoperations were significantly more common after SSF, both in any compartment, adjusted HR 5.0 (3.8 – 6.5), and in the apical compartment, adjusted HR 40.2 (21.6 – 74.7). This is a register based cohort study and as such selection bias is inevitable, yet adjustments in the analysis were made for BMI, age, smoking, preoperative POP-stage in apical compartment and previous surgery. It can also be noted that the group receiving treatment with Manchester procedure was more than 6 times as large as the group receiving treatment with SSF which might imply that surgeons in this study were more confident with the Manchester procedure.

Conclusion: For women receiving surgical treatment of apical prolapse, treatment with SSF compared with the Manchester procedure may lead to more reoperations, yet the size of the effect is uncertain (low certainty of evidence: GRADE ⊕⊕◯◯).

Recurrent prolapse (Appendix 4.5)
No studies.

Complications in comparative studies of sacrospinous fixation vs Manchester procedure
No studies.

Outcomes important for decision making

Dyspareunia (Appendix 4.6)
No studies.

Chronic pain (Appendix 4.7)
No studies.

Patient-reported tolerance of physical load
No studies.

Urinary incontinence including de novo (Appendix 4.8)
No studies.

Other outcomes of interest.

Operative time (Appendix 4.9)
No studies.

Length of hospital stay (Appendix 4.10)
No studies.

Duration of sick leave
No studies.

Results regarding laparoscopic sacrocolpopexy/sacrohysteropexy vs Manchester procedure

No studies comparing LSC/LSH with the Manchester procedure were identified regarding any of the chosen outcomes.

Complications reported in case series per surgical method (Appendix 4.11b)
Thirty-one studies were included as case series to evaluate complications.

Sacrospinous fixation
Thirteen studies evaluating complications after SSF were identified. Six studies reported on pelvic pain, thigh pain or gluteal pain with a frequency ranging from at lowest 1.2% in one study, around 6% reported in two studies, 23% in a large study with 11,570 patients, up to the highest frequency of 55.4% in a smaller study including 242 patients. The reported duration of pain varied considerably from immediate pain to pain lasting >6 months. Six studies reported on urinary tract complications such as difficulty voiding with a rate ranging from 0.3% to 10.5% and urinary tract infections ranging from 5.8% to 14.8%.

Laparoscopic sacrocolpopexy/sacrohysteropexy
Fourteen studies evaluating complications after LSC/LSH were identified. Five studies reported on overall complication rate ranging from 5.1% to 17.9%. Nine studies reported on venous thromboembolic complications with a frequency ranging from 0.1% to 0.4%.

Nine studies reported on surgical site infections with a frequency ranging from 0.4% to 1.4%. Eight studies reported on urinary tract infections with a frequency ranging from 3.1% to 3.6%.

Manchester procedure
Four studies evaluating complications after the Manchester procedure were identified. Two of these studies reported on urinary retention one with a rate of 2.4% and the other with a rate of 22.1%.

8. Organisational aspects

SSF has been the most used procedure for apical prolapse at Sahlgrenska University Hospital during the last decade. During the last years, Manchester procedure, an old technique that during the last decade had been used less and less, has gained increased interest and is now used more frequently. LSC/LSH has previously been used sparsely, whereas it for the last two years has been recommended to younger women as the first choice for surgical treatment of apical prolapse.

Thus, all techniques are in use, the choice mostly depending on the surgeons' own preferences. The choice to use the more advanced laparoscopic procedure, LSC/LSH, for younger women, is currently motivated by the findings in the previous systematic review (Maher et al., 2016), indicating that this technique should be associated with a lower risk for long-term relapse.

The results from this HTA report do not show compelling evidence for one technique being superior to another.

In Region Västra Götaland, LSC/LSH is only used at Sahlgrenska University Hospital, and to a small extent at the private clinic Carlanderska in Gothenburg. A few hospitals in Region Västra Götaland perform sacrocolpopexy as an open surgery procedure with a few cases per year. Currently, patients suitable for LSC/LSH are therefore referred to Sahlgrenska University Hospital from other hospitals to some extent. SSF and the Manchester procedure are used in most hospitals in Region Västra Götaland.

Since LSC/LSH is a more advanced operation technique, fewer surgeons have this competence. The demands of the operating theatre staff are higher. The operative time is longer compared with the other techniques, meaning that fewer patients can have surgery with unchanged resources. Another consequence is that it might need to be performed at fewer hospitals, compared with other techniques.

9. Economic aspects

Identification of currently used technologies

All three technologies are currently in use and costs are based on the cost per patient database from the Sahlgrenska University Hospital in years 2019 and 2020. The codes used to identify the technologies were:

- I1 - SSF: LEF53 (n=39), LEF96 (n=101). The mean cost per patient is calculated as the weighted average of the two codes.
- I2 - LSC/LSH: LEF97 (n=22)
- I3 - Manchester procedure: No code was deemed relevant for identification. Instead, patients were identified directly based on personal identification numbers from the clinic (n=16) and cost per patient data were retrieved for these patients.

Present costs of currently used technologies

The table below shows the mean cost per surgery using data from 2019 and 2020.

Intervention	Method	Mean cost per patient 2019 – 2020 (Swedish kronor, SEK)
I1	SSF	66 500
I2	LSC/LSH	117 800
I3	Manchester procedure	43 300

Note: costs are rounded to even thousand SEK.

It should be noted that the cost per patient data reported here is not adjusted for any potential selection into treatment.

The cost-effectiveness of technologies is based on comparing if the difference in costs can be motivated by reasonable differences in health outcomes (the Swedish ethical platform). From this perspective, LSC/LSH can be motivated if there are reasonable improvements in health outcomes compared to SSF and Manchester procedure. Such improvements were not identified in this HTA-report.

Total difference in costs

Based on the mean cost per patient and the number of patients undergoing SSF (n=63), LSC/LSH (n=13), and Manchester procedure (n=27) at Sahlgrenska University Hospital in 2019, the total cost is estimated to 5.9 million SEK. The table below shows the annual cost with different hypothetical mixes of technologies assuming that the cost differences reported above would hold in the other scenarios:

	SSF	LSC/LSH	Manchester procedure	Total cost per year
Current share	61%	13%	26%	6.9 million SEK
Scenario 1	80%	10%	10%	7.1 million SEK
Scenario 2	40%	30%	40%	8.2 million SEK
Scenario 3	10%	10%	80%	5.5 million SEK

Available economic evaluations or cost advantages/disadvantages

A total of 8 economic cost studies were identified, but most were not in line with the PICO since they compared different LSC/LSH techniques to each other or compared to transvaginal mesh. PICO-relevant studies include Lua et al. (2017) that compared costs of SSF to LSC/LSH using an observational registry-approach in a US healthcare setting and found that LSC/LSH was about $1,700 to $2,800 more expensive per patient. Ohno et al. (2016) conducted a cost-effectiveness analysis using a decision-analytic model comparing LSC/LSH to SSF. The modeling results indicated that LSC/LSH was about $2,000 more expensive per patient but led to 0.08 more quality-adjusted life years (QALYs) and the cost per gained QALY was about $25,000 (typically interventions with a cost per QALY below $50,000 is considered reasonable). But note that the study assumed slightly better health outcomes with LSC/LSH compared to SSF (regarding reoperation and recurrent prolapse). If this does not hold true, the conclusion on cost-effectiveness will change altogether.

10. Ethical aspects

The findings of this HTA report are that there are not enough studies to state that one surgical method is superior or inferior to the others. In this systematic review of the scientific literature comparing the above-described surgical techniques we conclude that there is low certainty of evidence for little or no difference in key clinical outcomes (ie awareness of prolapse, patient satisfaction, reoperation, quality of life) between vaginal techniques and laparoscopic surgery. The possible disadvantage of the LSC/LSH compared to the other methods is that it might require longer surgical time, and a higher cost per patient.

The three different surgical methods studied in this report are all at use at Sahlgrenska University Hospital. The choice of surgical method depends on the surgeon's preference and at this stage also the patient's age is taken into consideration, offering LSC/LSH to younger patients with apical prolapse, as previous reports suggested that the abdominal approach with sacrocolpopexy/hysteropexy might be the most durable over time and therefore the golden standard for surgical treatment for apical prolapse (Maher et al., 2016).

The findings of the HTA report that the LSC/LSH might have longer surgical time and a higher cost per patient, but no superiority in key outcomes, leads to the question if one should offer these surgeries outside of scientific research. In a time of limited resources, with long waiting time for surgical procedures, where access to surgical wards is the key element to shortening the queues, the actual surgical time is crucial. A longer surgical time leads to fewer patient being operated each day and therefore a slower shortening of the queues. There is also the economic aspect of the LSC/LSH to consider. Can we motivate a higher cost if the surgical technique is not proven superior to other, more cost-effective alternatives?

11. Discussion

Summary of main results

The aim of this review was to identify the most effective surgical technique with the least risk of adverse events to treat apical prolapse. However, there is a striking lack of comparative studies regarding these three surgical methods used to treat apical prolapse, even though prolapse is a common problem and women have a high life-time risk of undergoing prolapse surgery. The studies included show a wide heterogenicity regarding concomitant surgical procedures and comorbidity which makes it difficult to draw conclusions from the comparisons. Available comparative studies had a follow up time of days for studies reporting on perioperative outcomes up to follow up duration of 3.5 years. Of the three studies reporting on recurrence of prolapse, one study had a follow up time of 12 months, one study had a follow up time of 24 months and one study of 33 months. A vast majority of recurrent cases present within one year after surgery (Miedel et al., 2008) and 95% within two years (Culligan et al., 2002).

The main finding of this review is that there is a lack of sufficient evidence to suggest that one of the three studied surgical methods is superior to the others. One finding was the observation of longer surgical time for LSC/LSH compared to SSF. This observation is in line with the clinical experience and may of course be important in the choice of surgical method regarding economical, organisational and ethical aspects. Despite a large amount of literature, many studies used composite surgical procedures in their comparisons and were thus excluded from this review.

Overall completeness and applicability of evidence

Only six studies were found comparing SSF with LSC/LSH, one study comparing SSF with the Manchester procedure, looking only at the outcome reoperation, and no study comparing the Manchester procedure with LSC/LSH. This lack of studies might be partly due to the choice of excluding publications on abdominal open surgery when performing sacrocolpopexy, as well as vaginal mesh surgery. The reason for exclusion of open surgery is that laparoscopic technique is known to be superior when it comes to patient recovery, hospital stay and complications. Vaginal mesh surgery is internationally controversial due to complications and therefore used as a second line therapy at Sahlgrenska University Hospital. In Anglo-Saxon countries, vaginal mesh is abandoned.

Agreements and disagreements with other studies and reviews

This report suggests that there may be little or no difference when it comes to recurrence of prolapse after SSF and LSC/LSH. In contrast, Geoffrion and associates concluded in their recently published systematic review that there is moderate evidence that vaginal suspension techniques are inferior to sacrocolpopexy/sacrohysteropexy (open, laparoscopic or robot assisted) regarding objective recurrence of apical prolapse (Geoffrion et al., 2021). Maher and associates in the Cochrane review from 2016 conclude that abdominal sacrocolpopexy/ hysteropexy are associated with lower risk of recurrence of prolapse, awareness of prolapse, reoperation, dyspareunia and SUI than vaginal suspension techniques (Maher et al., 2016). However, in both these systematic reviews a variety of different vaginal suspension techniques were grouped together and compared with sacrocolpopexy/sacrohysteropexy.

Our aim was to go further and define and differentiate the specific techniques for apical prolapse in order to make the comparison more clinically applicable.

Implications for research

There is a need for well-designed randomised controlled trials and further studies to evaluate effectiveness, patient satisfaction and safety regarding different surgical methods to treat apical prolapse. To ensure clinical relevance it is important to use clearly defined surgical groups.

12. Future perspectives

Scientific knowledge gaps

This report reveals that there are still scientific knowledge gaps to have in mind when counselling a woman about different surgical methods to treat apical prolapse. There is a lack of high-quality studies comparing different surgical methods. The heterogeneity in the included cohort studies regarding comorbidity and concomitant surgical procedures, emphasizes the need for well-designed randomised controlled trials. All three methods addressed in this report seem to be improving symptoms of prolapse and health-related quality of life. However, if there are any differences in effectiveness and safety between the methods is still to be investigated.

Ongoing research

The search in Clinicaltrials.gov and WHO ICTRP database identified 246 ongoing clinical trials. Out of these seven are relevant according to the PICO of this report and are listed below.

Author Country	Estimated completion date	Study design	Study groups	Estimated patients (n)	Outcomes
Coolen The Netherlands	July 2018 Not yet published	Randomised controlled trial	Laparoscopic sacrocolpopexy, SSF (among women with vault prolapse)	74	UDI prolapse related symptoms, post-operative recovery, morbidity, sexual function, QoL, POP-Q re-interventions, costs and cost-effectiveness, complications.
Hsiao Taiwan	December 2023	Observational study	Sacrocolpopexy, SSF, transvaginal mesh repair, anterior colporrhaphy, posterior colporrhaphy	100	UDI-6 IIQ-7 psychosomatic score OABSS FSFI
Marcickiewicz Sweden	May 2015, Not yet published	Randomised controlled trial	Laparoscopic sacrocolpopexy, SSF	138	Anatomical failure, Continence status, sexual function, prolapse symptoms, QoL
Kluivers The Netherlands	February 2020, Not yet published	Randomised controlled trial	The Manchester procedure, SSF	424	composite outcome (combination of anatomy, symptoms and re-interventions) 2 years after surgery complications, pelvic floor dysfunctions, POP recurrence, further treatments, quality of life, costs
Svabik Czech Republic	October 2024, Not yet published	Randomised controlled trial	Laparoscopic Sacrocolpopexy, SSF, Transvaginal mesh procedure	462	Objective cure rate, recurrence of prolapse, de novo dyspareunia, mesh related complications, genital hiatus size, Distance of mesh from the bladder neck, Lowest position of the mesh, ICIQ-UI SF, POP-SS, PISQ-12, PFDI, TS-VAS, De novo SUI, de novo OAB, reoperation
Zhiyuan Dai China	December 2018 Not yet published	Cohort study	Laparoscopic sacrocolpopexy, SSF, Laparoscopic inguinal ligament suspension	300	POP-Q Pelvic MRI
Zhiyuan Dai China	December 2021 Still recruiting	Randomised controlled trial	Laparoscopic sacrocolpopexy, SSF	230	POP-Q, PFDI-20, PISQ-12, I-QoL, Complications

13. Participants in the project

The question was nominated by

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Patient representative

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Declaration of interests

Participants reported not having any conflict of interest considered relevant for the work on this project.

Project time

The HTA was accomplished during the period of March 23rd 2021 – February 17th 2022. Literature searches were made April 2021.

Appendix 1: PICO, study selection, search strategies, and references

Question(s) at issue: How do Laparoscopic sacrocolpopexy/sacrohysteropexy, sacrospinous fixation and the Manchester procedure compare, when it comes to effectiveness in treating apical prolapse, risk for adverse events and regarding costs for surgery?

PICO: (*P=Patient I=Intervention C=Comparison O=Outcome*)

P	Women receiving surgical treatment of apical prolapse
I	I1: **Sacrospinous fixation (SSF):** including both sacrospinous ligament fixation (SSLF) and sacrospinous hysteropexy (SSHP) (excluding procedures with vaginal mesh) I2: **Laparoscopic sacrocolpopexy/sacrohysteropexy (LSC/LSH):** including traditional laparoscopic technique, robotic assisted laparoscopic technique (robotic assisted sacrocolpopexy (RASC), and robotic assisted sacrohysteropexy (RASH)) I3: **Manchester procedure**
C	C1: **Sacrospinous fixation (SSF):** as in I1 above C2: **Laparoscopic sacrocolpopexy/sacrohysteropexy (LSC/LSH):** as in I2 above C3: **Manchester procedure**
O	<u>Critical for decision making</u> HRQL (preferably validated scales) Awareness of prolapse (subjective bulging symptoms/feeling of heaviness) Patient satisfaction Reoperation (any or same compartment) Recurrent prolapse (apical compartment) <u>Complications</u> <u>Important for decision making</u> Dyspareunia Chronic pain Patient-reported tolerance of physical load (lift, carry, run, exercise) Urinary incontinence (including de novo) <u>Other outcomes of interest</u> Operative time Duration of hospital stay Duration of sick leave

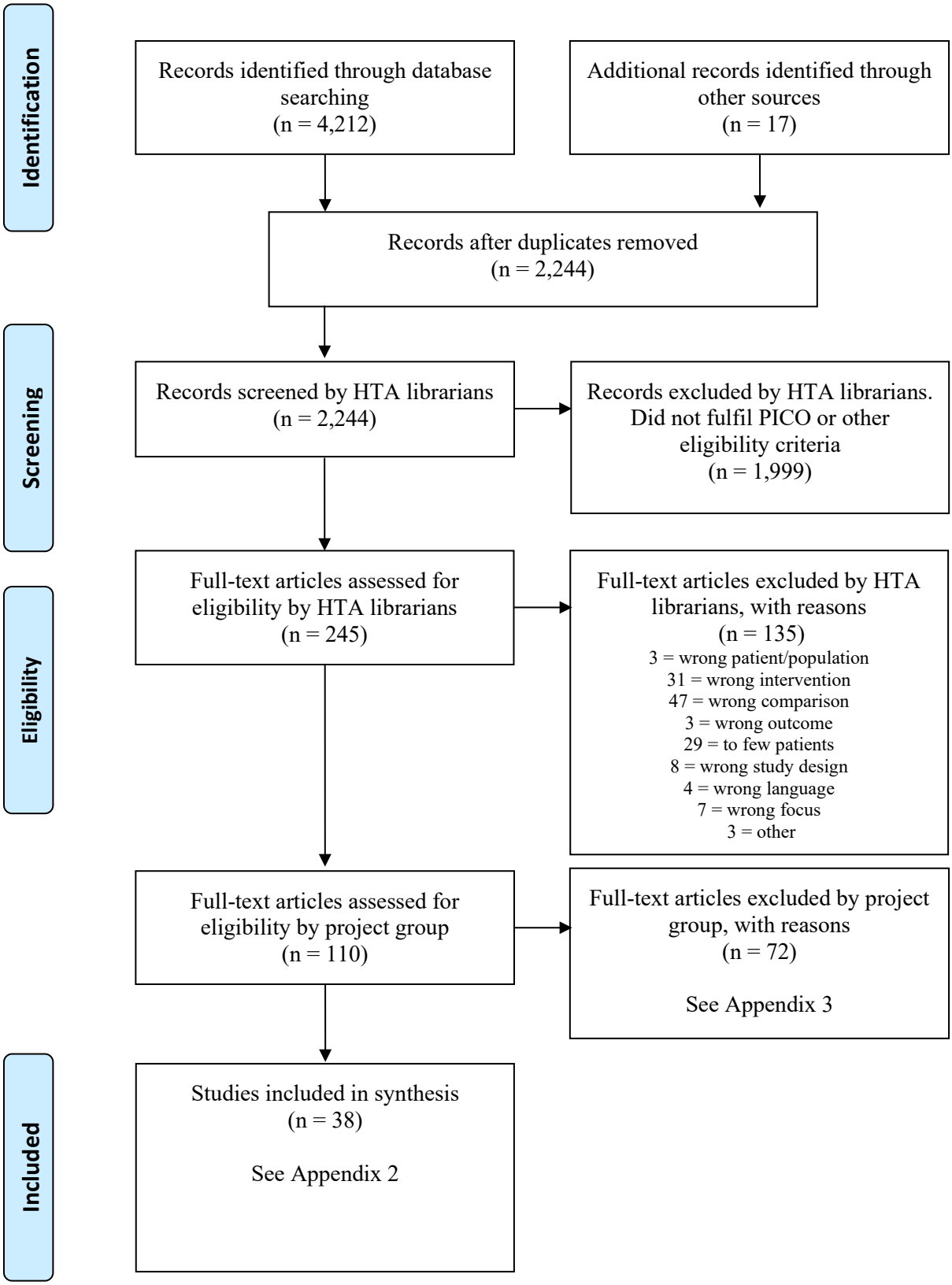
<u>Eligibility criteria</u>

Study design:
Systematic reviews
RCT
Non-randomised controlled studies with at least 20 patients /group
Case series for I1 and I3 with at least 200 patients (for information on complications)
Case series for I2 (minimally invasive surgery, sacral uteropexy/sacral colpopexy) with at least 1000 patients (for information on complications)

Language:
English, Swedish, Danish, Norwegian

Publication date:
RCT, non-randomised controlled studies and case series published from 1990 onwards
Systematic reviews from 2016 onwards

Selection process – flow diagram



Modified from Moher et al., 2009

Search strategies

Database: PubMed
Date: 1 Apr 2021
No. of results: 1,558

Search	Query	Results
#11	**Search: #8 NOT #9 Filters: Danish, English, Norwegian, Swedish**	**1,558**
#10	Search: #8 NOT #9	1,816
#9	Search: Editorial[ptyp] OR Letter[ptyp] OR Comment[ptyp] OR Case reports[ptyp]	3,890,011
#8	Search: #3 AND #7	2,140
#7	Search: #4 OR #5 OR #6	7,940
#6	Search: manchester*[tiab]	5,390
#5	Search: colpopex*[tiab] OR sacrocolpopex*[tiab] OR colposacropex*[tiab] OR perineopex*[tiab] OR colpoperineopex*[tiab] OR sacrocolpoperineopex*[tiab] OR hysteropex*[tiab] OR sacrohysteropex*[tiab] OR hysterosacropex*[tiab] OR uteropex*[tiab] OR sacrouteropex*[tiab] OR uterosacropex*[tiab] OR vaginopex*[tiab] OR sacrovaginopex*[tiab] OR vaginosacropex*[tiab] OR cervicopex*[tiab] OR sacrocervicopex*[tiab] OR cervicosacropex*[tiab] OR sacropex*[tiab]	2,006
#4	Search: sacrospin*[tiab] OR sacro-spin*[tiab]	849
#3	Search: #1 OR #2	37,494
#2	Search: prolapse*[tiab] OR POP[tiab] OR procidentia[tiab]	34,831
#1	Search: "Pelvic Organ Prolapse"[Mesh] Sort by: Most Recent	12,432

Database: Embase 1974 to 2021 March 31 (Ovid)
Date: 1 Apr 2021
No. of results: 2,039

#	Searches	Results
1	exp pelvic organ prolapse/	22699
2	(prolapse$ or POP or procidentia).ab,kw,ti.	51610
3	1 or 2	57067
4	exp sacrocolpopexy/	1433
5	(sacrospin$ or sacro-spin$).ab,kw,ti.	1867
6	(colpopex$ or sacrocolpopex$ or colposacropex$ or perineopex$ or colpoperineopex$ or sacrocolpoperineopex$ or hysteropex$ or sacrohysteropex$ or hysterosacropex$ or uteropex$ or sacrouteropex$ or uterosacropex$ or vaginopex$ or sacrovaginopex$ or vaginosacropex$ or cervicopex$ or sacrocervicopex$ or cervicosacropex$ or sacropex$).ab,kw,ti.	4615
7	manchester$.ab,kw,ti.	7462
8	4 or 5 or 6 or 7	13388
9	3 and 8	4957
10	limit 9 to (embase or medline)	2470
11	limit 10 to (article or article in press or conference paper or "review")	2320
12	**limit 11 to (danish or english or norwegian or swedish)**	**2039**

Database: The Cochrane Library
Date: 1 Apr 2021
No of results: 243 ref
Cochrane reviews: 3
Trials: 240

ID	Search	Hits

#1	MeSH descriptor: [Pelvic Organ Prolapse] explode all trees	586
#2	(prolapse* OR POP OR procidentia):ti,ab,kw (Word variations have been searched)	4233
#3	#1 OR #2	4242
#4	(sacrospin* OR (sacro NEXT spin*)):ti,ab,kw (Word variations have been searched)	231
#5	(colpopex* OR sacrocolpopex* OR colposacropex* OR perineopex* OR colpoperineopex* OR sacrocolpoperineopex* OR hysteropex* OR sacrohysteropex* OR hysterosacropex* OR uteropex* OR sacrouteropex* OR uterosacropex* OR vaginopex* OR sacrovaginopex* OR vaginosacropex* OR cervicopex* OR sacrocervicopex* OR cervicosacropex* OR sacropex*):ti,ab,kw (Word variations have been searched)	482
#6	(manchester*):ti,ab,kw (Word variations have been searched)	768
#7	#4 OR #5 OR #6	1387
#8	#3 AND #7	525
#9	(clinicaltrials or trialsearch):so	362791
#10	#8 NOT #9	420
#11	(conference abstract):pt	173424
#12	**#10 NOT #11**	**243**

Database: CINAHL, AMED, APA PsycInfo (EBSCOhost), Federated search
Date: 1 Apr 2021
No. of results: 372

#	Undran	Resultat
S8	**S1 AND S5** **Avgränsare - Dokumenttyp: Journal Article; Exkludera doktorsavhandlingar; Dokumenttyp: Journal Article, Report, Review; Publiceringstyp: Case Study, Clinical Trial, Journal Article, Meta Analysis, Meta Synthesis, Practice Guidelines, Randomized Controlled Trial, Research, Review, Systematic Review** **Language: - english**	**372**
S7	S1 AND S5 Avgränsare - Dokumenttyp: Journal Article; Exkludera doktorsavhandlingar; Dokumenttyp: Journal Article, Report, Review; Publiceringstyp: Case Study, Clinical Trial, Journal Article, Meta Analysis, Meta Synthesis, Practice Guidelines, Randomized Controlled Trial, Research, Review, Systematic Review	382
S6	S1 AND S5	454
S5	S2 OR S3 OR S4	5,862
S4	TI manchester* OR AB manchester*	5,057
S3	TI (colpopex* OR sacrocolpopex* OR colposacropex* OR perineopex* OR colpoperineopex* OR sacrocolpoperineopex* OR hysteropex* OR sacrohysteropex* OR hysterosacropex* OR uteropex* OR sacrouteropex* OR uterosacropex* OR vaginopex* OR sacrovaginopex* OR vaginosacropex* OR cervicopex* OR sacrocervicopex* OR cervicosacropex* OR sacropex*) OR AB (colpopex* OR sacrocolpopex* OR colposacropex* OR perineopex* OR colpoperineopex* OR sacrocolpoperineopex* OR hysteropex* OR sacrohysteropex* OR hysterosacropex* OR uteropex* OR sacrouteropex* OR uterosacropex* OR vaginopex* OR sacrovaginopex* OR vaginosacropex* OR cervicopex* OR sacrocervicopex* OR cervicosacropex* OR sacropex*)	657
S2	TI (sacrospin* OR sacro-spin*) OR AB (sacrospin* OR sacro-spin*)	219
S1	TI (prolapse* OR POP OR procidentia) OR AB (prolapse* OR POP OR procidentia)	9,986

The web-sites of **SBU** and **Folkehelseinstituttet** were visited
1 Apr 2021
Nothing relevant to the question at issue was found

Reference lists
A comprehensive review of reference lists brought 17 new records

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Project: Apical Prolapse

Appendix 2 – Characteristics of included studies

Author Year Country	Study Design in publication	Length of Follow-Up	Study Groups relevant for this report	Patients per study group (n)	Mean Age per study group (years)	Population Stage of prolapse, Previous hysterectomy BMI	Concomitant procedure (proportion % and type)	Outcome variables
Ayhan 2006 Turkey	Case series	5y (4 months-19 years) median (range)	MP	n = 204	34.68y (4.24) mean (SD)	Stage of prolapse: Grade 2: to the hymen: 13.7% Grade 3: Halfway out of the hymen: 86.3% Previous hysterectomy and BMI not reported	Tuballigation: 40.2% Kelly-Kennedy plication: 78.4% TVT: 2.9%	Complications
Brueseke 2020 USA	Cohort study		SSF LSC/LSH: robotic assisted procedure	SSF: n = 58 LSC/LSH: n = 207	SSF: not specified LSC/LSH: 60.6 y	SSF: BMI, stage of prolapse, previous hysterectomy not reported. LSC/LSH Stage of prolapse: POP-Q stage Stage 2: 40.8% Stage 3-4: 59.2% BMI: 27.3 (4.9) Previous hysterectomy not reported.	SSF: Not separately reported LSC/LSH: Hysterectomy: 29.5% Mid urethral sling: 51.5% Anterior colporrhaphy: 4.8% Posterior colporrhaphy: 41.3%	RBC transfusion perioperatively

Project: Apical Prolapse

Appendix 2 – Characteristics of included studies

Author Year Country	Study Design in publication	Length of Follow-Up	Study Groups relevant for this report	Patients per study group (n)	Mean Age per study group (years)	Population Stage of prolapse, Previous hysterectomy BMI	Concomitant procedure (proportion % and type)	Outcome variables
Campbell 2018 Sweden	Cohort Study (only one treatment group included in this HTA)	1 year	SSF	n = 584	Not separately reported	Stage of prolapse: Above/to hymen: 19.0% Beyond hymen: 66.0% Previous hysterectomy, BMI not separately reported	Anterior colporrhaphy: 33.9% Posterior colporrhaphy: 15.1% Anterior + posterior colporrhaphy: 28.3%	Complications
Chaudhry 2016 USA	Case series	30 days	LSC/LSH	n = 1201	61.3y (11.1) mean (SD)	Not reported	Not reported	Complications
Chen 2017 China	Cohort study	2 years	SSF LSC/LSH	SSF: n = 95 LSC/LSH: n = 113	SSF: 59.8 y LSC/LSH: 57.1 y	Stage of prolapse: POP-Q stage: SSF: Stage 2: 10.5% Stage 3: 82.1% Stage 4: 7.4% LSC/LSH: Stage 2: 23.0% Stage 3: 70.8% Stage 4: 6.2% Previous hysterectomy: SSF: 5.3%	Not reported	HRQoL Recurrence of POP Urinary incontinence Duration of hospital stay Chronic pain Operation time

Project: Apical Prolapse

Appendix 2 – Characteristics of included studies

Author Year Country	Study Design in publication	Length of Follow-Up	Study Groups relevant for this report	Patients per study group (n)	Mean Age per study group (years)	Population Stage of prolapse, Previous hysterectomy BMI	Concomitant procedure (proportion % and type)	Outcome variables
						LSC/LSH: 0.9% BMI: SSF: 24.1(2.6) LSC/LSH: 23.6(2.6) mean (SD)		
Clancy 2018 Canada	Cohort study (only one treatment group included in this HTA)	Not reported Reporting on perioperative outcomes	LSC/LSH	n = 7087	Not reported in total. Reported for the different groups 58y (12) 59y (11) mean (SD)	Stage of prolapse and previous hysterectomy not reported BMI: 28 (6) mean (SD)	Hysterectomy: 66.7% Vaginal repair: 0.27%	Complications
Cruikshank 2003 USA	Cohort study (only one treatment group included in this HTA)	3.6y (6 months-5 years) mean (range)	SSF	n = 695	61.5y (24-80y) mean (range)	Stage of prolapse and BMI not reported Previous hysterectomy: 57.4%	Hysterectomy: 42.6% Anterior colporrhaphy: 19.1% Posterior colporrhaphy: 12.7%	Complications

Project: Apical Prolapse

Appendix 2 – Characteristics of included studies

Author Year Country	Study Design in publication	Length of Follow-Up	Study Groups relevant for this report	Patients per study group (n)	Mean Age per study group (years)	Population Stage of prolapse, Previous hysterectomy BMI	Concomitant procedure (proportion % and type)	Outcome variables
							Perineorrhaphy: 6.2% Paravaginal defect repair: 11.2% Subvesical sling: 5.8% Retrorectal levatorplasty: 0.4% Anterior culdeplasty: 12.8% Suprapubic bladder catheter: 57.7% Posterior culdeplasty: 25.3% High cul-de-sac ligation: 57.7%	
Dandolu 2017 USA	Cohort study (only one treatment group included in this HTA)	2y minimum	LSC/LSH	n = 4552	53.2y (11.1) mean (SD)	Not reported	Hysterectomy: 1.7%	Complications
Doganay 2013 Germany	RCT (only one treatment group included in this HTA)	Not reported Reporting on perioperative outcomes	SSF	n = 1462	Not separately reported	Stage of prolapse:POP-Q stage Stage 3: 52.1% Stage 4: 48.0%	Anterior colporrhaphy: 97.6% Posterior colporrhaphy: 97.6%	Complications

Project: Apical Prolapse

Appendix 2 – Characteristics of included studies

Author Year Country	Study Design in publication	Length of Follow-Up	Study Groups relevant for this report	Patients per study group (n)	Mean Age per study group (years)	Population Stage of prolapse, Previous hysterectomy BMI	Concomitant procedure (proportion % and type)	Outcome variables
						BMI: <25: 14.9% 25-30: 75% >30: 10.1% Previous hysterectomy not reported	Paravaginal repair: 15.1% Oophorectomy: 6.0% Sling: 10.0% TOT: 23.5% Repair of enterocele: 2.5%	
Flack 2015 USA	Cohort study (only one treatment group included in this HTA)	Not reported	LSC/LSH: robotic assisted procedure	n = 14 601 (subgroup with robotic assisted procedure only)	60.4y (11) Mean (SD)	Not reported	Hysterectomy: 54% Sling: 10%	Complications
Halder 2017 USA	Cohort study (only one treatment group included in this HTA)	30 days	LSC/LSH	n =3548	<50y: 22.2% 50-59y: 27.8% 60-69y: 32.7% 70-79y: 15% ≤80y: 2.3%	BMI 27.0 (24.0-30.7) Med (Q1-Q3) Stage of prolapse and previous hysterectomy not reported.	Not reported	Complications

Project: Apical Prolapse

Appendix 2 – Characteristics of included studies

Author Year Country	Study Design in publication	Length of Follow-Up	Study Groups relevant for this report	Patients per study group (n)	Mean Age per study group (years)	Population Stage of prolapse, Previous hysterectomy BMI	Concomitant procedure (proportion % and type)	Outcome variables
Hefni 2006 UK	Case series	57 months (24–84) mean (range)	SSF	n = 305	59.9y (10.4) mean (SD)	Stage of prolapse: Post-hysterectomy vault prolapse 43% (The vault could be drawn to or past the hymenal ring after completion of the hysterectomy) Enterocele +/- first degree uterine prolapse 32% Second or third degree uterine prolapse 25% Previous hysterectomy: 43.6% BMI not reported	Hysterectomy: 38.4% Anterior colporrhaphy: 59.7% suburethral plication of the pubocervical ligaments:16.7% perineorraphy: 99.0%	Complications

Project: Apical Prolapse

Appendix 2 – Characteristics of included studies

Author Year Country	Study Design in publication	Length of Follow-Up	Study Groups relevant for this report	Patients per study group (n)	Mean Age per study group (years)	Population Stage of prolapse, Previous hysterectomy BMI	Concomitant procedure (proportion % and type)	Outcome variables
Hokenstad 2016 USA	Cohort study (only one treatment group included in this HTA)	30 days	LSC/LSH	N = 3346	58.7y (11.5) mean (SD)	BMI: 27.8 (5.5) mean (SD) Stage of prolapse and previous hysterectomy not reported	Not reported	Complications
Husby 2019 Denmark	Cohort study	43 months (median with range 1-90 months)	SSF MP	SSF n = 416 MP n = 2786	SSF 58.2 years MP 61.9 years	Stage of prolapse POP-Q-stage: SSHP Stage 0: 3.6% Stage 1:16.4% Stage 2: 57.5% Stage 3: 13.2% Stage 4: 4.1% MP Stage 0: 3.7% Stage 1: 12.1% Stage 2: 53.8% Stage 3: 15.2% Stage 4: 1.7% (missing data 13.8%) Previous hysterectomy was an exclusion criterion	No data available	Reoperation

Project: Apical Prolapse

Appendix 2 – Characteristics of included studies

Author Year Country	Study Design in publication	Length of Follow-Up	Study Groups relevant for this report	Patients per study group (n)	Mean Age per study group (years)	Population Stage of prolapse, Previous hysterectomy BMI	Concomitant procedure (proportion % and type)	Outcome variables
						BMI SSHP: <25: 46.4% 25-29: 30.1% 30-35: 8.4% >35: 3.4% BMI MP <25: 39.2% 25-29: 29.3% 30-35: 10.7% >35: 2.8% (missing data 18.1%)		
Izett-Kay 2020 UK	cross-sectional questionnaire study	46 months (2– 141 months) median (range)	LSC/LSH	n = 1121	58 y (24–86 y) (range)	Not reported	Not reported	Complications
Kisby 2021 USA	Cohort study (only one treatment group included in this HTA)	30 days	LSC/LSH	n = 2573	62.7y (10.3) mean (SD)	BMI: 28.0 (5.3) mean (SD) stage of prolapse, previous hysterectomy not reported	Concomitant sling: 29.6% Concomitant hysterectomy was an exclusion criterion.	Complications

Project: Apical Prolapse

Appendix 2 – Characteristics of included studies

Author Year Country	Study Design in publication	Length of Follow-Up	Study Groups relevant for this report	Patients per study group (n)	Mean Age per study group (years)	Population Stage of prolapse, Previous hysterectomy BMI	Concomitant procedure (proportion % and type)	Outcome variables
Kow 2016 USA	Cohort study	Perioperative outcomes	SSF LSC/LSH: LSH, RASH	SSF n = 20 LSH n = 43 RASH n = 27	Not separately reported	Previous hysterectomy was an exclusion criterion Not separately reported	Concomitant hysterectomy was an exclusion criterion Not separately reported	Operation time Estimated blood loss
Lantzsch 2001 Germany	Case series	4.8y (6 months-9 years) Mean (SD) Follow up data available for 123 patients.	SSF	n = 200	59.8 y (33-83 y) mean (range)	Stage of prolapse According to Beecham First degree: 10.5% Second degree: 56.5% Third degree: 19% Previous hysterectomy: 86% BMI not reported	Hysterectomy: 14% Resection of enterocele: 54.5% Anterior colporrhaphy: 44% Reconstruction of urogenital diaphragm 28.5% Colpoperineoplasty: 12% Posterior colporrhaphy: 11.5% Vaginal colposuspension according to Raz: 7.5% Abdominal colposuspension according to Burch: 3.5%	Complications

Project: Apical Prolapse

Appendix 2 – Characteristics of included studies

Author Year Country	Study Design in publication	Length of Follow-Up	Study Groups relevant for this report	Patients per study group (n)	Mean Age per study group (years)	Population Stage of prolapse, Previous hysterectomy BMI	Concomitant procedure (proportion % and type)	Outcome variables
Li 2014 USA	Cohort study (only one treatment group included in this HTA)	Not reported	LSC/LSH: robotic assisted procedure	n = 2381	63y (57-69) median (IQR)	Not reported	Not reported	Complications
Linder 2019 USA	Cohort study (only one treatment group included in this HTA)	30 days	LSC/LSH	n = 2538	64 (56–70) median (IQR)	BMI Underweight: 0.8% Normal: 27.6% Overweight:41.9% Obese: 29.7% Missing data: n = 13 Previous hysterectomy was an inclusion criterion Stage pf prolapse not reported.	urethral sling: 31.7%	Complications
Linder 2018 USA	Cohort study (only one treatment group included in this HTA)	30 days	LSC/LSH	n = 3183	63y (55-69) median (IQR)	Not reported	Posterior Repair: 3.6% Urethral Sling: 33.0% Hysterectomy: 8.2%	Complications

Project: Apical Prolapse

Appendix 2 – Characteristics of included studies

Author Year Country	Study Design in publication	Length of Follow-Up	Study Groups relevant for this report	Patients per study group (n)	Mean Age per study group (years)	Population Stage of prolapse, Previous hysterectomy BMI	Concomitant procedure (proportion % and type)	Outcome variables
Lovatis 2002 Canada	Case series	<1-5years. 200 followed more than 1 year.	SSF	n = 293	61.7 (30-88) mean (range)	BMI: 27.5 mean Prolapse grade: 3 median Previous hysterectomy: 54.6%	Hysterectomy: 54.0% Transvaginal cervical stump excision: 2.1% Posterior colporrhaphy: 100% Anterior colporrhaphy : 89.1% Buttress urethral sling: 48.8% Modified urethral sling: 38.9% Combined abdominovaginal urethral sling: 0.3% Enterocele repair: 21.8% Release LeForte:0.3% Martius graft: 2.0% Neourethra: 0.7% Repair urethrovaginal fistula: 0.7% Repair urethral diverticulum: 0.3% Excision Bartholin's cyst: 0.3% Anal sphincteroplasty: 0.3% Vaginal SOE: 19.5%	Complications

Project: Apical Prolapse

Appendix 2 – Characteristics of included studies

Author Year Country	Study Design in publication	Length of Follow-Up	Study Groups relevant for this report	Patients per study group (n)	Mean Age per study group (years)	Population Stage of prolapse, Previous hysterectomy BMI	Concomitant procedure (proportion % and type)	Outcome variables
							Laparoscopic SOE: 0.3% Laparascopic assisted vaginal SOE: 10.6%	
Lua 2017 USA	Cohort Study	90 days	SSF LSC/LSH	SSF: n = 17549 LSC/LSH: n = 10708	SSF: 53,2y (8.3) LSC/LSH: 50,6y (8.9) mean (SD)	Not reported	SSF: Hysterectomy: 33.4% LSC/LSH Hysterectomy: 68.7%	Complications
Marcickiewiz 2007 Sweden	Cohort Study	SSF: months: 38.4 (7-108) LSC/LSH: months: 33.6 (13-60) median (range)	SSF LSC/LSH	SSF: n = 51 LSC/LSH: n = 60	SSF: 66y (43-88) LSC/LSH: 58y (30-83) median (range)	Stage of prolapse Baden Walker-grade SSF Grade 1: 17.6% Grade 2: 31.4% Grade 3: 50.1% LSC/LSH Grade 1: 31.7% Grade 2: 18.3% Grade 3: 50% Previous hysterectomy was an inclusion criterion BMI	SSF: Anterior wall repair: 27.5% Posterior wall repair: 39.2% Enterocele repair: 56.9% TVT: 11.8% Stamey: 3.9% LSC/LSH: Anterior wall repair: 6.7% Posterior wall repair: 31.7% Enterocele repair: 3.3% Burch: 10%	Reoperation Awareness of prolapse Operation time Duration of hospital stay. Patient satisfaction Recurrent prolapse Dysparenuia

Project: Apical Prolapse

Appendix 2 – Characteristics of included studies

Author Year Country	Study Design in publication	Length of Follow-Up	Study Groups relevant for this report	Patients per study group (n)	Mean Age per study group (years)	Population Stage of prolapse, Previous hysterectomy BMI	Concomitant procedure (proportion % and type)	Outcome variables
						SSF: 27.9 (21-36.4) LSC/LSH: 24.1 (18-27) median(range)		
Mothes 2015 Germany	Cohort study (only one treatment group included in this HTA)	Within hospital admission time and up to 48h after discharge	SSF	n = 269	Not reported	Previous hysterectomy: 30.5% Stage of prolapse and BMI not reported	Hysterectomy: 65.7% Posterior repair: 100%	Complications
Ottesen 2004 Denmark	Cohort study (only one treatment group included in this HTA)	30 days	MP	n = 1813	Not reported	Not reported	posterior wall repair 42% Anterior wall repair 43% Anterior + posterior wall repair 14%	Complications
Oversand 2014 Norway	Cohort study (only one treatment group included in this HTA)	1y (5 y for reoperation)	MP	n = 431	67y median	Stage of prolapse: POP-Q stage: Stage 2: 36.6% Stage 3-4: 63.4%	Not reported	Complications

Project: Apical Prolapse

Appendix 2 – Characteristics of included studies

Author Year Country	Study Design in publication	Length of Follow-Up	Study Groups relevant for this report	Patients per study group (n)	Mean Age per study group (years)	Population Stage of prolapse, Previous hysterectomy BMI	Concomitant procedure (proportion % and type)	Outcome variables
Pollak 2007 USA	Cohort study (only one treatment group included in this HTA)	Not reported	SSF	n = 240	65.8y mean	Stage of prolapse Stage: 3 (1-4) median (range) Previous hysterectomy and BMI not reported	Hysterectomy: 45% Anterior repairs: 31% Posterior repairs: 85%	Complications
Sanses 2016 USA	Cohort study (only one treatment group included in this HTA)	12 months	SSF	n = 1642	73.9y (5.7) Mean (SD)	Not reported	Concomitant procedures 87.3% not stated which	Complications
Sauerwald 2011 Germany	Cohort study (only one treatment group included in this HTA)	Until discharge from hospital	SSF	n = 203	66.9y (9.6) mean (SD)	Stage of prolapse Ba +2.9 (4.3) Bp +3.6 (4.2) C +4.1 (4.3) TVL +9.1 (2.1) Mean Previous hysterectomy: 48% BMI 26 (4.5) mean (SD)	Hysterectomy 48% Anterior repair 79% Posterior repair 86% TVT or TOT 16%	Complications

Project: Apical Prolapse

Appendix 2 – Characteristics of included studies

Author Year Country	Study Design in publication	Length of Follow-Up	Study Groups relevant for this report	Patients per study group (n)	Mean Age per study group (years)	Population Stage of prolapse, Previous hysterectomy BMI	Concomitant procedure (proportion % and type)	Outcome variables
Slopnick 2019 USA	Cohort study (only one treatment group included in this HTA)	30 days	LSC/LSH	n = 1197	Not separately reported	Not separately reported	Not separately reported	Complications
Tolstrup 2018 Denmark	Cohort study (only one treatment group included in this HTA)	20-68 months	MP	n = 295	59.6y (13.0) Mean (SD)	Stage of prolapse: POP-Q stage: Stage 1: 1.3% Stage 2: 70.5% Stage 3: 25.8% Stage 4: 2.4% BMI: 25.7 (4.0) Mean (SD) Previous hysterectomy not reported.	Anterior colporrhaphy: 83% Posterior colporrhaphy: 20.3% Perineorrhaphy: 9.2%	Complications
Trochez 2018 UK	Cohort study (only one treatment group included in this HTA)	Not reported	LSC/LSH	n = 3016	59.45y (12.69) mean (SD)	BMI: 24.19 (9.53) Mean (SD) Stage of prolapse, Previous hysterectomy not reported	Not reported	Complications

Project: Apical Prolapse

Appendix 2 – Characteristics of included studies

Author Year Country	Study Design in publication	Length of Follow-Up	Study Groups relevant for this report	Patients per study group (n)	Mean Age per study group (years)	Population Stage of prolapse, Previous hysterectomy BMI	Concomitant procedure (proportion % and type)	Outcome variables
Tyson 2015 USA	Cohort study (only one treatment group included in this HTA)	30 days	LSC/LSH	n = 1127	≤51y: 24.4% 52-60 y: 27.6% 61-68 y: 26.9% ≥69 y: 21.1%	Stage of prolapse, Previous hysterectomy BMI Not reported	Hysterectomy: 0.2%	Complications
Unger 2014 USA	Case series	6 weeks	SSF	n = 242	66 y (10) Mean (SD)	BMI: 28.7 (5.4) mean (SD) Previous hysterectomy and stage of prolapse not reported.	concomitant procedures: Hysterectomy, mid urethral sling, anterior repair, posterior repair. Numbers of patients are not separately reported	Complications
Van Ijsselmuiden 2020 The Netherlands	RCT	12 months	SSF LSC/LSH	SSF: n = 62 LSC/LSH: n = 64	SSF: 60.76y (10.7) LSC/LSH: 61.08y (9.8) mean (SD)	Stage of prolapse: POP-Q- stage: SSF: Stage 2: 62.9% Stage 3: 30.6% Stage 4: 6.5% LSC/LSH: Stage 2: 70.3% Stage 3: 28.1% Stage 4: 1.6%	SSF: Anterior repair: 98.4% Posterior colporrhaphy: 86% Perineorrhaphy: 14% TVT: 1.6% LSC/LSH: Anterior repair: 85.9%	Recurrence of POP Reoperation HrQoL Awareness of prolapse Patient satisfaction Dyspareunia Urinary incontinence

Project: Apical Prolapse

Appendix 2 – Characteristics of included studies

Author Year Country	Study Design in publication	Length of Follow-Up	Study Groups relevant for this report	Patients per study group (n)	Mean Age per study group (years)	Population Stage of prolapse, Previous hysterectomy BMI	Concomitant procedure (proportion % and type)	Outcome variables
						BMI SSF: 26.6 (2.9) LSC/LSH: 26.6 (3.4) Mean (SD) Previous hysterectomy was an exclusion criterion	Laparoscopic posterior repair: 38% Posterior colporrhaphy: 38% Perineorrhaphy: 23% TVT: 3.1%	
Weinberg 2019 USA	Cohort study (only one treatment group included in this HTA)	30 days	LSC/LSH	n = 7232	58.8y (11.7) Mean (SD)	Stage of prolapse, Previous hysterectomy BMI not reported.	Not reported	Complications
Wu 2020 Taiwan	Case series	5.5y (24 months - 120 months) Mean (range)	SSF	n = 453	64.2y (±11.13) Mean (range)	Stage of prolapse POP-Q stage: Stage 1: 1.1% Stage 2: 29.8% Stage 3: 52.3% Stage 4: 16.8% Previous hysterectomy: 20.3%	Hysterectomy: 53.4% Anterior colporrhaphy: 75.3% Posterior Colporrhaphy: 78.6% Paravaginal repair: 6.2%	Complications

Project: Apical Prolapse

Appendix 2 – Characteristics of included studies

Author Year Country	Study Design in publication	Length of Follow-Up	Study Groups relevant for this report	Patients per study group (n)	Mean Age per study group (years)	Population Stage of prolapse, Previous hysterectomy BMI	Concomitant procedure (proportion % and type)	Outcome variables
						BMI: 25.8(± 4.08) Mean (range)		

Abbreviations: SSF: Sacrospinous fixation (including SSLF and SSHP), SSHP LSC/LSH: Laparoscopic sacrocolpopexy/sacrohysteropexy (including traditional laparoscopic and robotic assisted techniques, RASC/RASH), MP: Manchester procedure, POP-Q: pelvic organ prolapse quantification, BMI: Body mass index, SOE: salpingooforectomia, TVT: tension-free vaginal tape, TOT: transobturator tape

Project: Apical prolapse
Appendix 3.
Excluded articles

Author, year	Reason for exclusion
Alas, 2017	Wrong comparison
Anglés-Acedo, 2020	Wrong comparison: LSC vs anterior vaginal mesh. Case series n < 1000
Anonymos, 2019	Wrong kind of article: guideline
Antosh, 2020	Systematic review
Baessler, 2018	Systematic review
Baily, 1954	Case series not reporting on complications. Publication before 1990
Benson, 1996	Wrong comparison: SSLF vs Open abdominal SC. Case series n < 200
Bataller, 2019	Wrong comparison: LSC vs anterior vaginal mesh. Case series n < 1000
Bideau, 2021	Wrong intervention: Anterior vaginal mesh w/wo midurethral sling
Borahay 2020	Not concurrent with pico: evaluating association of preoperative pain with post-operative pain.
Boysen, 2017	Both laparoscopic and open abdominal sacrocolpopexies, outcome not presented in relation to technique
Breton, 2021	Wrong intervention, SSLF with mesh
Bretschneider, 2021	SSLF and ileococcygeus suspension in the same cohort, outcome not presented in relation to technique
Caliskan, 2018	Wrong intervention: Vaginal mesh surgery
Chang, 2019	Wrong intervention: SSLF with mesh
Cheng, 2019	Wrong comparison: LCS vs vaginal mesh vs colpoclesis vs colporaphy. Case series n < 1000
Conger, 1958	Publication before 1990
Coolen, 2017	Systematic review
Costantini, 2016	Method review
De Tayrac, 2008	Wrong comparison: SSLF vs infracoccygeal sacropexy. Case series n < 200
Engelbredt, 2020	Wrong outcome: evaluating cervical and uterine malignancies after manchester-procedure.
Eto, 2019	Wrong outcome, transient voiding dysfunction
Geoffrion, 2021	Systematic review
Gluck, 2020	Method review
Grevez, 2020	Systematic review
Gupta, 2016	Wrong intervention and comparison: Both open and laparoscopic SC vs transvaginal procedure, outcome not presented in relation to technique.
Halaska, 2012	Wrong comparison: SSLF vs transvaginal mesh. Case series n < 200
Hall, 2021	Outcome not presented in relation to technique
Himmler, 2021	Wrong intervention: SSLF with mesh
Himmler, 2021	Wrong intervention: SSLF with mesh
Hoke, 2019	Review
Husby, 2018	Wrong comparison: Manchester procedure vs Vaginal hysterectomy+ Uterosacral ligament supesntion. Secondary analysis of data.
Iversen, 1981	Wrong population: 20% without apical prolapse

Project: Apical prolapse
Appendix 3.
Excluded articles

Author, year	Reason for exclusion
Kanasaki, 2020	Wrong comparison: LSC vs transvaginal mesh vs native tissue repair. Outcome not presented in relation to technique. Case series n < 1000
Kapoor, 2017	Systematic review
Kenne, 2020	Operation method not specified.
Kurian, 2021	Wrong outcome: cervical and endometrial cancer.
Larson, 2013	Case series not reporting on complications
Li, 2020	Wrong comparison: LSC vs transvaginal mesh. Case series n < 1000
Liedl, 2018	Wrong intervention: SSLF with mesh
Liu, 2014	Wrong comparison: LSC vs total vaginal mesh. Case series n < 1000
Lo, 2015	Wrong intervention: Vaginal mesh surgery
Lo, 2017	Wrong intervention: Vaginal mesh surgery
Maher, 2011	Wrong comparison: LSC vs total vaginal mesh surgery. Case series n < 1000
Maher, 2012	Wrong comparison: LSC vs total vaginal mesh surgery. Case series n < 1000
Maher. 2016	Systematic review
Martin, 2015	Wrong comparison: RASC vs SSLF with mesh: Case series n < 1000
Meriwether, 2018	Systematic review
Meriwether, 2019	Systematic review
Myoga, 2021	Wrong comparison: LSC vs transvaginal mesh vs hysterectomy+colpocleisis vs laparoscopic native-tissue repair. Case series n < 1000
Ng, 2019	Wrong comparison: SSLF vs hysterectomy and SSLHP. Case series n < 200
Obinata, 2018	Wrong comparison: LSC vs Vaginal mesh surgery. Case series n < 1000
O´leary. 1970	Publication before 1990
Otubo, 1982	Case series n < 200
Paraiso, 1996	Case series n < 200
Ramanah, 2012	Wrong comparison: LSC vs Vaginal mesh + SSLF. Case series n < 1000
Rubin, 1966	Publication before 1990
Sanses, 2009	Not concurrent with PICO: vaginal mesh surgery vs open ASC vs uterosacral ligament suspension.
Seitz, 2020	Not concurrent with PICO: SSHP with mesh vs SSHP with allograft
Siddiqui, 2012	Wrong comparison
Svabik, 2014	Wrong comparison: SSLF vs vaginal mesh surgery. Case series n < 200
Szymczac, 2019	Systematic review
Tan, 2014	Wrong intervention: SSLF + vaginal mesh
Tibi, 2019	Wrong comparison: LSC vs vaginal mesh surgery vs native tissue repair. Outcome not presented in relation to technique in native tissue repair arm. Case series n < 1000
To, 2017	Wrong comparison: LSC vs vaginal mesh surgery. Case series n < 1000
Tolstrup, 2017	Systematic review

Project: Apical prolapse
Appendix 3.
Excluded articles

Author, year	Reason for exclusion
Wan, 2020	Wrong comparison: LSC/LSH vs vaginal mesh surgery. Case series n < 1000
Wang, 2019	Wrong comparison: LSC vs vaginal mesh surgery. Case series n < 1000
Wei, 2019	Wrong comparison: LSC vs vaginal mesh surgery. Case series n < 1000
Wu, 2018	Not concurrent with PICO: Abdominal mesh vs abdominal native tissue vs vaginal mesh vs vaginal native tissue. Outcome not presented in relation to technique in abdominal native tissue arm
Yadav, 2021	Wrong comparison: MISC vs open ASC vs vaginal colpopexy. Outcome not presented in relation to technique in vaginal colpopexy arm. Case series n < 1000
Zhang, 2020	Systematic review

Project: Apical Prolapse
Appendix 4.1
Outcome variable: Health related Quality of Life

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients per study group (n)	Not treated as allocated Withdrawals - dropouts	Instrument	Pre-OP		Post-OP		p-value	Comments	Directness *	Study limitations *	Precision *
					SSF	LSC/LSH	SSF	LSC/LSH					
Sacrospinous fixation vs Laparoscopic sacrocolpopexy / sacrohysteropexy													
van Ijsselmuiden 2020 Netherlands, Belgium	RCT	SSF n = 62 LSC/LSH n = 64	Not allocated treatment: SSF: 0 LSC/LSH: 6 Lost to follow up at 12 months SSF: 4 LSC/LSH: 5	**Short form-36**						Post-OP collected 12 months after surgery. Values are medians (interquartile ranges). P-values based on post-OP comparison SF 36 – scores ranging from 0 – 100, where a high score indicates a better quality of life in the respective domain. The urogenital distress inventory ranges from 0 – 100 where a high score indicates more	?	?	+
				Physical functioning	70 (50–85)	70 (55-85)	90 (79–95)	90 (78–95)	0.434				
				Social functioning	88 (63–100)	88 (75–100)	100 (88–100)	100 (88–100)	0.512				
				Role limitations physical	75 (0–100)	75 (29–100)	100 (75–100)	100 (100–100)	0.776				
				Role limitations emotional	100 (92–100)	100 (83–100)	100 (100–100)	100 (100–100)	0.857				
				Mental health	80 (68–92)	84 (68–88)	87 (76–96)	88 (76–92)	0.809				
				Vitality	70 (50–80)	65 (54–78)	80 (69–90)	75 (60–80)	0.097				
				Bodily pain	78 (45–90)	78 (57–90)	100 (78–100)	90 (78–100)	0.629				
				General health perception	70 (54–81)	70 (60–80)	78 (64–90)	75 (60–90)	0.928				
				Health change	50 (25–50)	50 (25–50)	75 (50–100)	75 (50–100)	0.693				
				Urogenital distress inventory									
				Overactive bladder	22 (11–47)	22 (6–44)	0 (0–11)	11 (0–22)	0.012				
				Urinary incontinence	17 (0–33)	25 (0–33)	0 (0–17)	17 (0–33)	0.057				
				Obstructive micturition	33 (0–50)	16 (0–33)	0 (0–17)	0 (0–0)	0.188				
				Genital prolapse	67 (33–67)	58 (33–67)	0 (0–0)	0 (0–0)	0.251				

Project: Apical Prolapse
Appendix 4.1
Outcome variable: Health related Quality of Life

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients per study group (n)	Not treated as allocated Withdrawals - dropouts	Instrument	Pre-OP		Post-OP		p-value	Comments	Directness *	Study limitations *	Precision *
					SSF	LSC/LSH	SSF	LSC/LSH					
				Pain	33 (0–50)	17 (0–33)	0 (0–17)	0 (0–17)	0.691	bothersome symptoms.			
				Defecatory distress inventory									
				Obstipation	0 (0–17)	0 (0–17)	0 (0–0)	0 (0–0)	0.779	The defecatory distress inventory ranges 0 – 100, where a high score indicates more bothersome symptoms.			
				Obstructive defecation	0 (0–8)	0 (0–17)	0 (0–8)	0 (0–8)	0.758				
				Pain	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)	0.123				
				Incontinence	0 (0–0)	0 (0–17)	0 (0–0)	0 (0–17)	0.017				
				Flatus	33 (0–33)	33 (0–67)	0 (0–33)	33 (0–33)	0.144				
				Incontinence impact questionnaire									
				Mobility	22 (0–44)	22 (6–39)	0 (0–11)	0 (0–17)	0.616	The incontinence impact questionnaire ranges 0 – 100, where a high score indicates more bothersome symptoms.			
				Physical	33 (0–33)	33 (0–33)	0 (0–0)	0 (0–0)	0.746				
				Social	0 (0–22)	0 (0–17)	0 (0–0)	0 (0–0)	0.740				
				Embarrassment	0 (0–33)	16 (0–17)	0 (0–0)	0 (0–0)	0.862				
				Emotion	11 (0–33)	11 (0–33)	0 (0–0)	0 (0–11)	0.298				
				PISQ-12	35 (32–40)	35 (32–39)	39 (34–42)		0.252	PISQ-12 scores from 0, indicating the			

Project: Apical Prolapse
Appendix 4.1
Outcome variable: Health related Quality of Life

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients per study group (n)	Not treated as allocated Withdrawals - dropouts	Instrument	Pre-OP		Post-OP		p-value	Comments	Directness *	Study limitations *	Precision *
					SSF	LSC/LSH	SSF	LSC/LSH					
								39 (37–42)		poorest sexual functioning to 48, indicating the best sexual function. EuroquoL 5 collected but not reported			
Chen 2017 China	Cohort study	SSF n =95 LSC/LSH n =113	Dropouts SSF n = 1 LSC/LSH n = 0	PFDI-20 score POPDI-6 score CRADI-8 score UDI-6 score	48.1 ± 47.7 24.4 ± 20.4 6.7 ± 9.8 17.6 ± 15.5	43.3 ± 23.7 23.0 ± 14.4 5.7 ± 5.9 14.7 ± 11.2	2 year follow-up 18.2 ± 14.8 9.0 ± 8.7 2.9 ± 5.5 6.3 ± 11.9	2 year follow-up 19.2 ± 24.5 6.1 ± 7.4 3.7 ± 8.9 9.4 ± 10.9	 0.717 0.287 0.478 0.376	Functional outcomes were evaluated by the Chinese versions of the Short Form-20 Pelvic Floor Distress Inventory, PFDI-20; range 0–80, with higher scores indicating worse function P-values based on post-OP comparison	?	?	-

Project: Apical Prolapse
Appendix 4.1
Outcome variable: Health related Quality of Life

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients per study group (n)	Not treated as allocated Withdrawals - dropouts	Instrument	Pre-OP		Post-OP		p-value	Comments	Directness *	Study limitations *	Precision *
					SSF	LSC/LSH	SSF	LSC/LSH					
Sacrospinous fixation vs Manchester procedure													
No studies included													
Laparoscopic sacrocolpopexy / sacrohysteropexy vs Manchester procedure													
No studies included													

Abbreviations: PFDI-20, Pelvic Floor Distress Inventory-Short Form 20; SSF: Sacrospinous fixation (including SSLF and SSHP), LSC/LSH: Laparoscopic sacrocolpopexy / sacrohysteropexy (including traditional laparoscopic and robotic assisted techniques (robotic assisted sacrocolpopexy (RASC) and robotic assisted sacrohysteropexy (RASH)), POPDI-6, Pelvic Organ Prolapse Distress Inventory 6; CRADI-8, Colorectal-Anal Distress Inventory 8; UDI-6, Urinary Distress Inventory 6. a Values are given as mean ± SD unless indicated otherwise

Project: Apical Prolapse
Appendix 4.2
Outcome variable: Awareness of prolapse

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design in publication	Number of patients per study group (n)	Not treated as allocated Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Sacrospinous fixation vs Laparoscopic sacrocolpopexy/sacrohysteropexy									
				SSF	**LSC/LSH**				
Van Ijsselmuiden 2020 The Netherlands	RCT	SSF: n = 62 LSC/LSH: n = 64	Not allocated treatment: SSF: 0 LSC/LSH: 6 Lost to follow up at 12 months SSF: 4 LSC/LSH: 5	0/58	0/59 n. s	Method of assessment: UDI (genital prolapse) 12 months after surgery	?	?	-
Marcickiewiz 2007 Sweden	Cohort study	SSF: n = 51 LSC/LSH: n = 60	Withdrawals not reported	n =6 (11.8%)	n =13 (21.7%) n. s	Time of follow-up 38.4 (7-108) months (median, range) in the SSF group, and 33.6 (13-60) months (median, range) in the LSC/LSH group	+	-	-
Sacrospinous fixation vs Manchester procedure									
No studies included									
Laparoscopic sacrocolpopexy/sacrohysteropexy vs Manchester procedure									
No studies included									

Abbreviations: SSF: Sacrospinous fixation (including SSLF and SSHP), LSC/LSH: Laparoscopic sacrocolpopexy/sacrohysteropexy (including traditional laparoscopic and robotic assisted techniques, RASC/RASH), UDI: urogenital distress inventory n.s: not significant

Project: Apical Prolapse
Appendix 4.3
Outcome variable: Patient satisfaction

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design in publication	Number of patients per study group (n)	Not treated as allocated Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Sacrospinous fixation vs Laparoscopic sacrocolpopexy/sacrohysteropexy									
				SSF	**LSC/LSH**				
Ijsselmuiden 2020 The Netherlands	RCT	SSF: n = 62 LSC/LSH: n = 64	Not allocated treatment: SSF: 0 MIS: 6 Lost to follow up at 12 months SSF: 4 MIS: 5	52/58 (89.7%) n.s.	50/58 (86.2%)	12 months after surgery Definition not described in publication.	?	?	+
Marcickiewiz 2007 Sweden	Cohort study	SSF: n = 51 LSC/LSH: n = 60	Withdrawals not reported	82% n.s.	78%	Only percentage satisfied provided in publication. Based on subjective success rate from 1 (very unsatisfied) to 10 (very satisfied) on a visual analogue scale, grades from 8 to 10 defined as very satisfied.	+	-	-
Sacrospinous fixation vs Manchester procedure									
No studies included									
Laparoscopic sacrocolpopexy/sacrohysteropexy vs Manchester procedure									
No studies included									

Abbreviations: SSF: Sacrospinous fixation (including SSLF and SSHP), LSC/LSH: Laparoscopic sacrocolpopexy / sacrohysteropexy (including traditional laparoscopic and robotic assisted techniques (robotic assisted sacrocolpopexy (RASC) and robotic assisted sacrohysteropexy (RASH)),

Project: Apical Prolapse
Appendix 4.4
Outcome variable: Reoperation (any or same compartment)

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design in publication	Number of patients per study group (n)	Not allocated treatment Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Sacrospinous fixation vs Laparoscopic sacrocolpopexy/sacrohysteropexy									
				SSF	**LSC/LSH**				
Van Ijsselmuiden 2020 The Netherlands	RCT	SSF: n = 62 LSC/LSH: n = 64	Not allocated treatment: SSF: 0 MIS: 6 Lost to follow up at 12 months SSF: 4 MIS: 5	Any compartment 3/61 (4.9%) Difference 1.8 (95% CI -5.1 to 8.7) Apical compartment 2/61 (3.3%) Difference 3.3 (95% CI -1.2 to 7.7)	Any compartment 2/64 (3.1%) Apical compartment 0/64 (0%)	12 months follow-up Analysed as ITT with LOCF	?	?	+
Marcickiewiz 2007 Sweden	Cohort study	SSF: n = 51 LSC/LSH: n = 60	Withdrawals not reported	4% n =2	20% n =12 p = 0.015	11.7% (n = 7) In LSC/LSH group and 0% (n = 0) in SSF group had another SSF or LSC/LSH. The rest had an anterior or posterior repair	+	-	-
Sacrospinous fixation vs Manchester procedure									
				SSF	**MP**				
Husby 2019 Denmark	Cohort study	SSF n = 416 MP n = 2786		Apical compartment 55/416 (13.2%) aHR 40.2 (95% CI 21.6 – 74.7) Any compartment 90/416 (21.6%) aHR 5.0 (95% CI 3.8 – 6.5)	Apical compartment 15/2786 (0.5%) Any compartment 171/2786 (6.1%)	Adjustments of HR made for BMI, age, smoking, preoperative POP-stage in apical compartment and previous surgery in anterior and posterior compartment.	+	+	+

Project: Apical Prolapse
Appendix 4.4
Outcome variable: Reoperation (any or same compartment)

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design in publication	Number of patients per study group (n)	Not allocated treatment Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Laparoscopic sacrocolpopexy/sacrohysteropexy vs Manchester procedure									
No studies included									

Abbreviations: SSF: Sacrospinous fixation (including SSLF and SSHP), LSC/LSH: Laparoscopic sacrocolpopexy / sacrohysteropexy (including traditional laparoscopic and robotic assisted techniques (robotic assisted sacrocolpopexy (RASC) and robotic assisted sacrohysteropexy (RASH)),, MP: Manchester procedure, ITT: intention to treat, LOCF: Last observation carried forward, aHR: adjusted hazard ratio

Project: Apical Prolapse
Appendix 4.5
Outcome variable: Recurrent prolapse (in apical compartment)

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design in publication	Number of patients per study group (n)	Not treated as allocated Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Sacrospinous fixation vs Laparoscopic sacrocolpopexy/sacrohysteropexy									
				SSF	**LSC/LSH**				
Ijsselmuiden 2020 The Netherlands	RCT	SSF: n = 62 LSC/LSH: n = 64	Not allocated treatment: SSF: 0 MIS: 6 Dropouts SSF: 4 MIS: 11 (10 missing POP-Q scores; 5 missing questionnaires)	ITT with complete cases 2/58 (3.4%) Difference: 2% (95% CI: -4.3% to 7.5%) ITT with LOCF 2/61 (3.3%) Difference: 1.7% (95% CI: -3.7% to 7.1%) Per protocol analysis 3.4% n = 2/58 Difference: 1.3% (95% CI: -4.9% to 7.1%)	ITT with complete cases 1/54 (1.9%) ITT with LOCF 1/64 (1.6%) Per protocol analysis 2.1% n = 1/47	Defined 12 months postop as a composite of: recurrent apical prolapse ≥ POP-Q stage 2 and bothersome protrusion/bulging symptoms and/or requiring therapy (surgery or pessary) No significant differences.	?	?	+
Chen 2017 China	Cohort study	SSF n =95 LSC/LSH n =113	SSF Missing:1	5.3% n = 5/94	4.4% n = 5/113	Recurrence in apical compartment At 1-year follow-up, apical compartment success was recorded for 89/94 (94.7%) in the SSF group and for 108/113 (95.6%) in the LSC/LSH group.	?	?	-
Marcickiewiz 2007 Sweden	Cohort study	SSF: n = 51 LSC/LSH: n = 60	Withdrawals not reported	0/51	0/60 7/60 (12%) p-value: 0.015	At the follow-up visit there was no recurrence of vault prolapse in either of the groups. 7 reoperations in LSC/LSH group were performed shortly after the initial operation due to failure of the technique.	+	-	-

Project: Apical Prolapse
Appendix 4.5
Outcome variable: Recurrent prolapse (in apical compartment)

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design in publication	Number of patients per study group (n)	Not treated as allocated Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Sacrospinous fixation vs Manchester procedure									
No studies included									
Laparoscopic sacrocolpopexy/sacrohysteropexy vs Manchester procedure									
No studies included									

Abbreviations: SSF: Sacrospinous fixation (including SSLF and SSHP), LSC/LSH: Laparoscopic sacrocolpopexy / sacrohysteropexy (including traditional laparoscopic and robotic assisted techniques (robotic assisted sacrocolpopexy (RASC) and robotic assisted sacrohysteropexy (RASH)),, POP-Q: Pelvic organ prolapse quantification, ITT: intention to treat, LOCF: Last observation carried forward, RCT: Randomized controlled trial,

Project: Apical Prolapse
Appendix 4.6
Outcome variable: Dyspareunia

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design in publication	Number of patients per study group (n)	Not treated as allocated Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Sacrospinous fixation vs Laparoscopic sacrocolpopexy/sacrohysterpexy									
				SSF	**LSC/LSH**				
Van Ijsselmuiden 2020 The Netherlands	RCT	SSF: n = 62 LSC/LSH: n = 64	Not allocated treatment: SSF: 0 LSC/LSH: 6 Lost to follow up at 12 months SSF: 4 LSC/LSH: 5	13/39 (33.3%) De novo 5/39 (13.2%)	5/37 (13.5%) p = 0.042 De novo 3/37 (8.1%) n. s.	Results for the subgroup of sexually active group	?	?	-
Marcickiewiz 2007 Sweden	Cohort study	SSF: n = 51 LSC/LSH: n = 60	Withdrawals not reported	5/20 (25%)	9/32 (28.1%) n. s.	Only 20 in the SSF group and 32 in the LSC/LSH group were sexually active and comfortable answering the question about dyspareunia	+	-	-
Sacrospinous fixation vs Manchester procedure									
No studies included									
Laparoscopic sacrocolpopexy/sacrohysterpexy vs Manchester procedure									
No studies included									

Abbreviations: : SSF: Sacrospinous fixation (including SSLF and SSHP), LSC/LSH: Laparoscopic sacrocolpopexy / sacrohysteropexy (including traditional laparoscopic and robotic assisted techniques (robotic assisted sacrocolpopexy (RASC) and robotic assisted sacrohysteropexy (RASH)), n.s: not significant

Project: Apical Prolapse
Appendix 4.7
Outcome variable: Chronic pain

*	+ No or minor problems
	? Some problems
	- Major problems

Author year country	Study design in publication	Number of patients per study group (n)	Not treated as allocated Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Sacrospinous fixation vs laparoscopic sacrocolpopexy/sacrohysteropexy									
				SSF	**LSC/LSH**				
Chen 2017 China	Cohort study	SSF n =95 LSC/LSH n =113	No dropouts	8 (8.4%) complained of pain which was mainly relieved within 6 weeks.	13 (11.5%) complained of pain which diminished gradually after 6 months.		?	?	-
Sacrospinous fixation vs Manchester procedure									
No studies included									
Laparoscopic sacrocolpopexy/sacrohysteropexy vs Manchester procedure									
No studies included									

Abbreviations: SSF: Sacrospinous fixation (including SSLF and SSHP), LSC/LSH: Laparoscopic sacrocolpopexy/sacrohysteropexy (including traditional laparoscopic and robotic assisted techniques, RASC/RASH)

Project: Apical Prolapse
Appendix 4.8
Outcome variable: Urinary incontinence (including de novo)

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design in publication	Number of patients per study group (n)	Not treated as allocated Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Sacrospinous fixation vs Laparoscopic sacrocolpopexy / sacrohysteropexy									
				SSF	**LSC/LSH**				
Van Ijsselmuiden 2020 The Netherlands	RCT	SSF n = 62 LSC/LSH n = 64	Not allocated treatment: SSF: 0 MIS: 6 Lost to follow up at 12 months SSF: 4 MIS: 5	UDI-score - Urinary incontinence Pre-op: 17 (0–33) Post-op: 0 (0–17) UDI-score – overactive bladder Pre-op: 22 (11–47) Post-op: 0 (0–11) de-novo OAB symptoms: n=0	UDI-score- Urinary incontinence Pre-op: 25 (0–33) Post-op: 17 (0–33) Between group difference at post-op: n. s. UDI-score – overactive bladder Pre-op: 22 (6–44) Post-op: 11 (0–22) Between group difference at post-op: p-value: 0.012 de-novo OAB symptoms: n = 2(4%)	The urogenital distress inventory scores range from 0 – 100 where a high score indicates more bothersome symptoms. Median (interquartile range)	?	?	+
Chen 2017 China	Cohort study	SSF n =95 LSC/LSH n =113	dropouts SSF n = 1 MIS n = 0	Overall SUI: 13/95 (13.8%) De novo SUI: 8/95(11.4%)	Overall SUI: 27/113 (23.9%) Between group difference: n. s. De novo SUI: 21/113 (23.8%) Between group difference: n. s.		?	?	-
Sacrospinous fixation vs Manchester procedure									
No studies included									
Laparoscopic sacrocolpopexy / sacrohysteropexy vs Manchester procedure									
No studies included									

Abbreviations: SSF: Sacrospinous fixation (including SSLF and SSHP), LSC/LSH: Laparoscopic sacrocolpopexy / sacrohysteropexy (including traditional laparoscopic and robotic assisted techniques (robotic assisted sacrocolpopexy (RASC) and robotic assisted sacrohysteropexy (RASH)),, OAB: Over active bladder SUI: stress urinary incontinence, n. s.: not significant

Project: Apical Prolapse
Appendix 4.9
Outcome variable: Operative time

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design in publication	Number of patients per study group (n)	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention Mean (SD) minutes	Control Mean (SD) minutes				
Sacrospinous fixation vs Laparoscopic sacrocolpopexy/sacrohysteropexy									
				SSF	**LSC/LSH**				
Chen Y 2017 China	Cohort study	SSF n =95 LSC/LSH n =113	No dropouts	119.9 (30.5) mean (SD)	157.8 (72.1) mean (SD) p-value <0.001	Operative time in minutes	?	?	-
Kow 2016 USA	Cohort study	SSF: n = 20 LSC/LSH: n =70: (traditional LSH n = 43 RASH n = 27)	No dropouts	160 (56) mean (SD)	Traditional LSH: 285 (77) p-value < 0.001 RASH: 345 (60) p-value < 0.001 mean (SD)	Total operating room time in minutes, from induction of anaesthesia to end of procedure. Concomitant procedures not separately reported p-values not reported in publication	+	-	-
Marcickiewiz 2007 Sweden	Cohort study	SSF: n = 51 LSC/LSH: n = 60	No dropouts	62 (30-137) Median (range)	129 (45-235) Median (range) p-value: 0.001	Time from incision until placement of last suture in minutes.	+	-	-
Sacrospinous fixation vs Manchester procedure									
No studies included									
Laparoscopic sacrocolpopexy/sacrohysteropexy vs Manchester procedure									
No studies included									

Abbreviations: : SSF: Sacrospinous fixation (including SSLF and SSHP LSC/LSH: Laparoscopic sacrocolpopexy/sacrohysteropexy (including traditional laparoscopic and robotic assisted techniques, RASC/RASH), LSH: Laparoscopic sacrohysteropexy, RASH: Robotassisted Sacrohysteropexy

Project: Apical Prolapse
Appendix 4.10
Outcome variable: Length of hospital stay

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design in publication	Number of patients per study group (n)	Not treated as allocated Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Sacrospinous fixation vs laparoscopic sacrocolpopexy/sacrohysteropexy									
				SSF	**LSC/LSH**				
Chen 2017 China	Cohort study	SSF n =95 LSC/LSH n =113	No dropouts	10.6 (3.0) Mean (SD)	1.5 (2.6) Mean (SD) p-value <0.001	Duration of hospital stay in days	-	?	-
Marcickiewiz 2007 Sweden	Cohort study	SSF : n = 51 LSC/LSH : n = 60		3.7 (1–18) Median (range)	4.0 (2–21) Median (range)	Duration of hospital stay in days	-	-	-
Sacrospinous fixation vs Manchester procedure									
No studies included									
Laparoscopic sacrocolpopexy/sacrohysteropexy vs Manchester procedure									
No studies included									

Abbreviations: SSF: Sacrospinous fixation (including SSLF and SSHP LSC/LSH: Laparoscopic sacrocolpopexy/sacrohysteropexy (including traditional laparoscopic and robotic assisted techniques, RASC/RASH)

Project: Apical Prolapse
Appendix 4.11 a Data from studies with control group
Outcome variable: Complications

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients per study group (n)	With-drawals - dropouts	Results		Comments
				Intervention	Control	
Sacrospinous fixation vs Laparoscopic sacrocolpopexy/sacrohysteropexy						
				SSF	**LSC/LSH**	
Brueseke 2020 USA	Cohort study	SSF: n = 58 LSC/LSH: n = 207		Patients receiving post-OP blood transfusion: 1.7% n = 1	Patients receiving post-OP blood transfusion: 0.5% n = 1	All procedures in the LSC/LSH group were robotic assisted
Kow 2016 USA	Cohort study	SSF n = 20 LSC/LSH: n = 60 (traditional LSH n = 43 RASH n = 27)		Estimated blood loss, mean (SD) in ml: 89 (100)	Estimated blood loss, mean (SD) in ml: Traditional LSH: 136 (102) RASH: 113 (78)	
Lua 2017 USA	Cohort study	SSF: n = 17549 LSC/LSH: N = 10708		Patients with readmission within 90 days: 4.22% (*95% CI:* 3.93-4.53)	Patients with readmission within 90 days: 4.64% (*95% CI:* 4.26-5.06) p-value: 0.0411	
Sacrospinous fixation vs the Manchester procedure						
No included studies						
Laparoscopic sacrocolpopexy/sacrohysteropexy vs the Manchester procedure						
No included studies						

Abbreviations: SSF: Sacrospinous fixation (including SSLF and SSHP), SSHP LSC/LSH: Laparoscopic sacrocolpopexy/sacrohysteropexy (including traditional laparoscopic and robotic assisted techniques, RASC/RASH), LSH: Laparoscopic sacrohysteropexy, RASH: Robotic assisted Sacrohysteropexy

Project: Apical Prolapse
Appendix 4.11 b Data from case series
Outcome variable: Complications

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design in publication (note, in this report all studies in this appendix only contributed as case series)	Number of patients in study group (n) relevant to this report	Withdrawals - dropouts	Results	Comments
Sacrospinous fixation					
Campbell 2018 Sweden	Cohort study (only one treatment group included in this HTA)	n = 548		Readmitted to hospital 4,2% (n = 23) Bleeding > 500 ml: 0.9% (n = 5)	Readmitted to hospital used as surrogate marker for complication. Not specified any further. No statistically significant difference between the two groups where different suturing techniques were used
Cruikshank 2003 USA	Cohort study (only one treatment group included in this HTA)	n = 695	n = 22	Bleeding 1.2% (n= 8) UTI 5.8% (n = 40) Abscess 1.4% (n = 10) Fever 1.4% (n = 10)	
Dandolu 2017 USA	Cohort study (only one treatment group included in this HTA)	n = 11,570		Dyspareunia 4.7% (n= 547) Pelvic pain 23.6% (n= 2734) Pain in thigh 4.2% (n= 483	
Doganay 2013 Turkey	RCT (only one treatment group included in this HTA)	n = 1464 (762+702)		Reop for Bleeding 1.1% (n = 9) Hemorrage 1.1% (n = 16) Hematoma 0.6% (n = 9) Bowel injury 0.5% (n = 4) Bladder injury 0.7% (n = 5) Nerve damage 1.4% (n = 11) Gluteal pain 1.2% (n= 18) Ureteral damage 0.1% (n = 1)	SSF performed with either Deschamps lig carrier or Aksakal instrument.

Project: Apical Prolapse
Appendix 4.11 b Data from case series
Outcome variable: Complications

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design in publication (note, in this report all studies in this appendix only contributed as case series)	Number of patients in study group (n) relevant to this report	Withdrawals - dropouts	Results	Comments
Hefni 2005 United Kingdom	Case series	n = 305		Rectal injury 0.6% (n=2) Blood transfusion 0.3% (n = 1) Vault hematoma 2.5% (n = 7) Re-suturing of anterior vaginal wall 0.3% (n = 1) Voiding difficulty 0.3% (n = 1) Buttock pain 6.5% (n = 20) Sensory loss on the back of the thigh 0.3% (n = 1)	
Lantzsch 2001 Germany	Case series	n = 200		Urinary tract infection 8.0% (n = 16) Temporary irritation of the sciatic nerve 7.5% (n = 15) Temporary partial ureteral obstruction 5.5% (n = 11) Blood loss less than 400 ml 3.5% (n = 7)	
Lovatis 2002 Canada	Case series	n = 293	n = 40 not seen beyond six weeks	Right buttock pain 6.1% (n = 18), persisting >6months in 3 patients De-novo Dyspareunia 3.8% (n =8) SUI: 3.1% (n = 9) Surgical site hematoma 0.3% (n =1) New-onset fecal incontinence 5.6% (n = 14) Right foot drop 0.3% (n = 1) spontaneously resolved by 6 weeks	
Mothes 2015 Germany	Cohort study (only one treatment group included in this HTA)	n = 269		Clavien-Dindo 1: 4.1% (n = 11) Clavien-Dindo 2: 14.1% (n = 38) Clavien-Dindo 3: 0.4% (n = 4) perioperative complication, rectal lesion: 1 (proved to be a precancerous lesion)	

Project: Apical Prolapse
Appendix 4.11 b Data from case series
Outcome variable: Complications

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design in publication (note, in this report all studies in this appendix only contributed as case series)	Number of patients in study group (n) relevant to this report	Withdrawals - dropouts	Results	Comments
Pollak 2007	Cohort study (only one treatment group included in this HTA)	N=240	NA	Intraoperative (due to needle placement) 5.0% (n=12) UTI 7.1% (n = 17) Febrile morbidity 3.8% (n = 9) Reoperation 1.7% (n = 4) Transfusion 5.0% (n = 12) Nerve injury 1.7% (n = 4)	Retrospective chart review.
Sanses 2016	Cohort study (only one treatment group included in this HTA)	N=1642	NA	Ileus, bowel obstruction 1.0% (n = 16) Bowel injury 0.4% (n = 6) Bladder injury 3.2% (n = 52) Ureter injury 1.6% (n = 27) Urinary dysfunction 10.5% (n = 172) Vascular injury 0.1% (n = 2) Medial complication (pulmonary, cardiovascular, renal) 4.4% (n = 72) UTI 14.8% (n = 242) SSI 3.7% (n = 61) Thromboembolism 0.9% (n = 15) Pain 7.5% (n = 123)	Retrospective cohort study using Medicare data in women ≥65 years.
Sauerwald 2011	Cohort study (only one treatment group included in this HTA)	n =203	NA	Urinary infection treated with antibiotics 6.4% (n = 13) Hematoma requiring surgical intervention 1.5% (n = 3) Postoperative voiding dysfunction 5.4% (n = 11) Infection treated with antibiotics 1.5% (n = 3) Mortality 0.5% (n = 1)	Retrospective cohort study including all SSF procedures done during six years in a German clinic.

Project: Apical Prolapse
Appendix 4.11 b Data from case series
Outcome variable: Complications

* + No or minor problems
? Some problems
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Author year country	Study design in publication (note, in this report all studies in this appendix only contributed as case series)	Number of patients in study group (n) relevant to this report	Withdrawals - dropouts	Results	Comments
Unger 2014 USA	Retrospective cohort study (only one treatment group included in this HTA)	n = 242	lost to follow-up n = 7	Immediate gluteal or posterior thigh pain: 55.4% (49.1%-61.5%) Gluteal or posterior thigh pain at 6 weeks15.3% (11.3%-20.4%) Required intervention for pain 2.1% (0.8%-4.7%) (3 patients had physical therapy, 1 patient had trigger point injection. 1 patient had both physical therapy and trigger point injection.) Resolution of pain was reported between 3 and 12 months	All patients underwent SSF with the Capio device.
Wu 2020 Taiwan	Case series	n = 453		Perioperative blood loss: 92.3 ml (91.4) Pain Score VAS postop 6 hours: 3.17 (0.9) Pain Score VAS postop 36 hours: 1.58 (0.5) Mean (SD)	All patients underwent unilateral SSF with veronikis ligature carrier.
Laparoscopic sacrocolpopexy/sacrohysteropexy					
Chaudry 2016 USA	Cohort study (only one treatment group included in this HTA)	n = 1201		Urinary tract infection 3.4% (n=41) Readmission to hospital 2.6% (n=31) Return to OR 1.5% (n=18) Specified: Deep surgical site infection 0,2% (n=2) Deep vein thrombosis 0.2% (n=3) Myocardial infarction 0.2% (n=3) Organ/space surgical site infection 0.2% (n=3) Pneumonia 0.2% (n=3) Pulmonary embolism 0 Renal insufficiency progressive 0.2% (n=3) Sepsis 0.2% (n=2) Septic shock 0.1% (n=1) Stroke 0.1% (n=1) Transfusion postoperatively 0.6% (n=7) Wound occurrences 0.4% (n=5)	The number of patients with complications and readmitted patients differ presumably because not all patients were treated in-hospital

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Clancy 2018 Canada	Cohort study (only one treatment group included in this HTA)	n = 7097	NA	Composite outcome 3,2 % (n=227) Surgical site infection: Superficial 0.7% (n=47) Deep incisional 0.2% (n=12) Organ/space 0.5% (n=32) Bleeding transfusion 1.0% (n = 68) Return to OR within 30 days 1.4% (n=99) Urinary tract infection 3.4% (n=238) Peripheral neurologic injury: 0 Sepsis 0.3% (n=21) Wound disruption: 0	The composite outcome includes any one of: SSI, bleeding transfusions, return to the OR within 30 days or prolonged length of total surgical stay more then 48 h.
Flack 2015 USA	Cohort study (only one treatment group included in this HTA)	n = 14 601		Inhospital complication 8% (n = 1098) Urinary complication 0.5% (n = 74) Hematoma or seroma 0.7% (n = 101) Digestive complication 0.9% (n =129) Respiratory complication 0.9% (n =129) Cardiac complication 0.4% (n = 64)	
Halder 2017 USA	Cohort study (only one treatment group included in this HTA)	n =3548		Blood transfusion 1.2% (n =41) Deep vein thrombosis 0.2% (n= 6) Superficial infection 0.7% (n=24) Deep infection 0.15% (n=5) Readmission 2.6% (n=82)	
Hokenstad 2016 USA	Cohort study (only one treatment group included in this HTA)	n = 3346		VTE 0.24 % (n = 8) (5 with DVT, 2 with PE, and 1 with DVT + PE.) One death in a patient with DVT + PE.	

Project: Apical Prolapse
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Izett-Kay 2020 United Kingdom	Cross-sectional questionnaire study	n = 1121.	1766 eligible participants, 1121 women responded (response proportion 63.5%),	The incidence of mesh complications requiring removal of hysteropexy mesh was 0.4% The rate of reoperation for apical prolapse was 3.7%, and for any form of pelvic organ prolapse it was 13.6%. The rate of chronic pain service use was 1.8%	
Kisby 2021 USA	Cohort study (only one treatment group included in this HTA)	n = 2573		Any complication 5.5% (n =141) Urinary tract infection 3.1% (n = 80) Superficial SSI 0.8 (n = 20) Cardiac complication 0.2% (n = 4) DVT/thrombophlebitis 0.1% (n = 3) Respiratory complication 0.4% (n = 10) Renal complications 0.2% (n = 5) Neurological complications 0.0% (n = 1) Sepsis/septic shock 0.3% (n = 8) Deep incisional SSI/organ space SSI 0.4% (n = 10) Wound disruption n = 0 Death within 30 days 0.0% (n = 1) Blood transfusion within 72 h 0.5% (n = 12) Reoperation related to primary procedure 1.3% (n = 27) Readmission related to primary procedure 1.8% (n =46)	

Project: Apical Prolapse
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Li 2014 USA	Cohort study (only one treatment group included in this HTA)	n = 2381	NA	Blood transfusion 0.7% (n = 16) Intraoperative complications 6% (n =143) Postoperative complications in total 17.9% (n = 427) Postop cardiac complications 2.4% (n = 58) Postop vascular complications 0.2% (n = 5) Postop wound complications 0.4% (n = 10) Postop genitourinary complications 4.9% (n = 117) Postop neurological 1.1% (n = 26) Postop infections 0.2% (n = 5) In hospital mortality 0.2% (n = 5)	
Linder 2018 USA	Cohort study (only one treatment group included in this HTA)	n = 3183		Overall 30-day complications 5.1% (n = 162) Major complications: Cardiac 0.2% (n = 7) DVT 0.2% (n = 6) LE 0.2% (n = 5) Sepsis 0.4% (n = 11) Respiratory 0.5% (n = 12) Renal 0.2% (n = 6) Neurological 0.1% (n = 2) Deep infection 0.5% (n = 15) Wound disruption 0% (n = 1) Minor complications: UTI 3.1% (n = 100) Superficial wound infection 0.7% (n = 22) Blood transfusion 0.5% (n = 15) Readmission 2.0% (n = 63) Reoperation 1.1% (n = 36) 30-day mortality 0% (n = 1)	

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Linder 2019 USA	Cohort study (only one treatment group included in this HTA)	N = 2538		Minor complications 3.9% (n = 100) UTI 3.3% (n = 84) Superficial SSI 0.7% (n = 18) Major complications 1.3% (n = 33) Cardiac 0.2% (n = 4) DVT 0.1% (n = 3) PE 0.2% (n = 4) Sepsis 0.3% (n = 8) Respiratory 0.4% (n = 10) Renal 0.2% (n = 5) Neurologic 0% (n = 1) Deep SSI 0.5% (n = 12) Wound disruption 0 (0%) Blood transfusion 0.5% (n = 13) Readmission 2.5% (n = 55) Reoperation 1.6 (n = 40) 30-day Mortality 0% (n = 1)	
Slopnick 2018	Cohort study (only one treatment group included in this HTA)	n =1197		Any complication 6.5% (n = 78) UTI 3.4% (n = 41) Superficial SSI 0.8% (n = 9) Reintubation 0.3% (n = 4) Blood transfusion 1.6% (n = 19) Unplanned readmission 2.0% (n = 22) Unplanned reoperation 1.1% (n = 13)	Register data from American College of Surgeons National Surgical Quality Improvement Program database.

Project: Apical Prolapse
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Trochez 2018 UK	Cohort study (only one treatment group included in this HTA)	n = 3016		Ureteric: 0.1% Bladder: 1.4% Vaginal: 1.1% Bowel: 0.3% Vascular: 0.1% Blood loss > 500 ml: 0.3% Blood transfusion: 0.1% Thromboembolism: 0.1%	
Tyson 2015 USA	Cohort study (only one treatment group included in this HTA)	n = 1127		Superficial SSI: 0.4% Deep SSI: 0% Organ space SSI: 0.6% Dehiscence: 0% Pneumonia: 0.3% Unplanned reintubation: 0.1% Pulmonary embolism: 0.1% Fail to wean vent within 48 h: 0% Acute renal failure: 0% Urinary tract infection: 3.6% Cerebrovascular accident: 0.1% Peripheral nerve injury: 0% Myocardial infarction: 0.2% Blood transfusions: 0.8% Deep venous thrombosis: 0% Sepsis: 0.2% Unplanned readmission: 1.4% Unplanned return to operating room: 1.4% 30-day mortality: 0.1%	This study comperes 30-day outcomes after LSC/LSH and open sacrocolpopexy/hysteropexy.

Project: Apical Prolapse
Appendix 4.11 b Data from case series
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Weinberg 2019 USA	Cohort study (only one treatment group included in this HTA)	n = 7232		Death: 0.06% Cardiac arrest: 0.06% Myocardial infarction: 0.08% Pneumonia: 0.21% Renal insufficiency: 0.07% Renal failure: 0.06% Pulmonary embolism: 0.18% DVT or thrombophlebitis: 0.15% Unplanned reoperation: 1.44% Superficial SSI:0.73% Deep incisional infection: 0.18% Organ space infection: 0.46% Systemic sepsis: 0.25% Septic shock: 0.14% Ventilator dependence for 48h: 0.08% Unplanned reintubation: 0.14% Wound disruption: 0.06% CNS deficit or cerebral accident: 0.04% Urinary tract infection: 3.25% Post-operative transfusion: 0.76%	

Project: Apical Prolapse
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Manchester procedure					
Ayhan 2006 Turkey	Cohort study (only one treatment group included in this HTA)	n = 204		Bladder perforation 0.98% (n = 2) Febrile morbidity 13.23% (n = 27) Retroperitoneal hematoma 0.49% (n = 1) Urinary retention 22.05% (n = 45) Cervical stenosis 11.27% (n = 23)	23 patients (11.27%) developed cervical stenosis, and cervical dilatation under general anesthesia was performed for symptomatic and therapeutic relief. Of these patients, 12 (5.88%) required cervical dilatation once; 5 (2.45%) required it twice, 3 (1.47%) required it 3 times, and 3 (1.47%) required it 4 times. One year after the Manchester operation, 1 patient (0.49%) underwent abdominal hysterectomy because of recurrent cervical stenosis after cervical dilatation failed 4 times
Ottesen 2004 Denmark	Cohort study (only one treatment group included in this HTA)	n = 1813		Reoperations within 30 days 3.2% (n = 58) Readmissions within 30 days 5.8% (n = 105)	
Oversand 2014 Norway	Cohort study (only one treatment group included in this HTA)	n = 431		De novo urgency incontinence 5.0% (n = 20/402) De novo stress incontinence 3.0% (n = 12/402) De novo mixed incontinence 0.5% (n = 2/402) Total de novo urinary incontinence 8.5% (n = 34/402) Dyspareunia 8.9% (n = 35/393) Postop hematoma 5.1% (n = 21/414) Postop infection 0.7% (n = 3/414) Reoperation rate 1 year 0.9% (n = 4/431) Reoperation rate 5 years 2.8% (n = 12/431)	

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Tolstrup 2018 Denmark	Cohort study (only one treatment group included in this HTA)	n = 295		Urinary retention: 2.4% Hematometra/pyometra 1% Antibiotic treatment in hospital: 1.7% Superficial vaginal bleeding: 0.7% Obstruction of ureter requiring surgery: 0.3% Bleeding >500 ml: 0% Bladder lesion: 0%	This study comperes the MP and vaginal hysterectomy with the main outcome recurrent or de novo POP.

Abbreviations: SSF: Sacrospinous fixation (including SSLF and SSHP), LSC/LSH: Laparoscopic sacrocolpopexy/sacrohysteropexy (including traditional laparoscopic and robotic assisted techniques, RASC/RASH) MP: Manchester procedure, UTI: urinary tract infection, SUI: stress urinary incontinence, SSI: Surgical site infection, NA: not applicable, DVT: deep venous thrombosis, PE: Pulmonary embolism, POP: pelvic organ prolapse

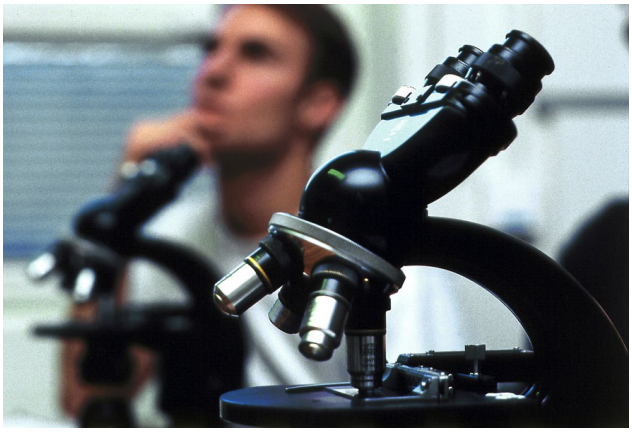
Innehållsdeklaration

Denna HTA-rapport är baserad på följande moment:

- [x] Metodbeskrivning
- [x] PICO
- [x] Uttömmande litteratursökning
- [x] Flödesschema
- [x] Urval relevans
- [x] Kvalitetsgranskning
- [x] Tabelldata
- [x] Sammanvägning av resultat
- [ ] Metaanalys
- [x] Evidensgradering enligt GRADE
- [x] Sammanfattning
- [x] Ekonomi
- [x] Organisation
- [x] Etik
- [x] Pågående studier
- [x] Exkluderade artiklar
- [x] Expertgrupp deltar
- [x] Extern granskning
- [x] Kunskapsluckor identifierade
- [x] Jävsdeklaration inhämtad från projektdeltagarna

Region Västra Götaland, HTA-centrum

Health Technology Assessment
Regional activity-based HTA



HTA

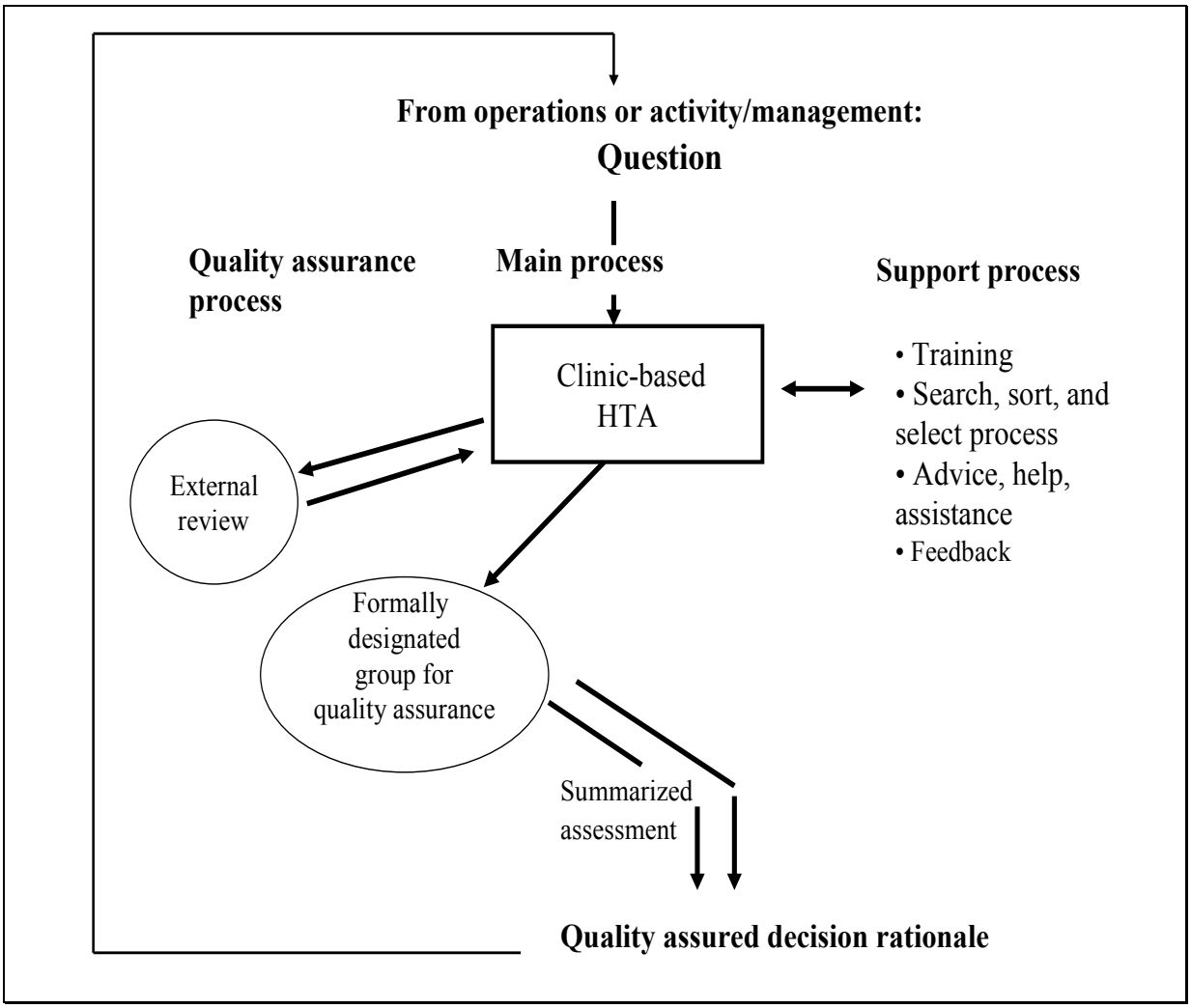
Health technology assessment (HTA) is the systematic evaluation of properties, effects, and/or impacts of health care technologies, i.e. interventions that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care.

To evaluate the certainty of evidence the Centre of Health Technology Assessment in Region Västra Götaland is currently using the GRADE system, which has been developed by a widely representative group of international guideline developers. According to GRADE the level of evidence is graded in four categories:

High certainty of evidence	= (GRADE⊕⊕⊕⊕)
Moderate certainty of evidence	= (GRADE ⊕⊕⊕O)
Low certainty of evidence	= (GRADE ⊕⊕OO)
Very low certainty of evidence	= (GRADE ⊕OOO)

In GRADE there is also a system to rate the strength of recommendation of a technology as either “strong” or “weak”. This is presently not used by the Centre of Health Technology Assessment in Region Västra Götaland. However, the assessments still offer some guidance to decision makers in the health care system. If the level of evidence of a positive effect of a technology is of high or moderate quality it most probably qualifies to be used in routine medical care. If the level of evidence is of low quality the use of the technology may be motivated provided there is an acceptable balance between benefits and risks, cost-effectiveness and ethical considerations. Promising technologies, but a very low quality of evidence, motivate further research but should not be used in everyday routine clinical work.

Christina Bergh
Professor, MD
Head of HTA-centrum


From operations or activity/management:
Question
Quality assurance process
Main process
Support process
Clinic-based HTA
• Training
• Search, sort, and select process
• Advice, help, assistance
• Feedback
External review
Formally designated group for quality assurance
Summarized assessment
Quality assured decision rationale

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