

# Surgical treatment for apical vaginal prolapse

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# Impact paragraph

Pelvic organ prolapse (POP) is a frequently occurring health issue, which can cause bothersome symptoms that may include vaginal bulge, pelvic pressure, and symptoms related to bladder or bowel dysfunction.<sup>1-4</sup> In addition, POP may negatively affect sexuality, body image, and quality of life.<sup>4,5</sup> The prevalence has been reported as high as 25 – 60% in parous women.<sup>1,2,6,7</sup> Moreover, the overall incidence of POP is still rising as a result of ageing and increasing obesity rates.<sup>2</sup> The lifetime risk of women undergoing a single surgery for POP or urinary incontinence is 19 – 20%.<sup>8,9</sup>

The relevance of research on the treatment of POP is self-explanatory when considering factors as the high and increasing prevalence, the impact of the symptoms, and the need for treatment. In this chapter the main outcomes of our studies will be summarised. Furthermore, the importance of this thesis and how it can contribute scientifically and societally will be explained.

## **Aim of the thesis and main outcomes**

The aim of this dissertation was to investigate which surgical treatment options are the most optimal for patients with post-hysterectomy vaginal vault prolapse or patients with uterine descent. In addition, we examined which patient-related and physician-related factors are important to Dutch gynaecologists when surgically treating patients with apical prolapse.

Based on our research discussed in this thesis, we conclude the following:

- Laparoscopic sacrocolpopexy is the preferred technique compared to open abdominal sacrocolpopexy for the treatment of post-hysterectomy vaginal vault prolapse, based on short-term advantages. On average, patients had less blood loss and a shorter hospital stay after the laparoscopic procedure, compared with the abdominal technique. There was no difference in disease-specific quality of life, anatomical outcome, the quantity of complications, and the number of surgical reinterventions at one-year follow-up and after long-term follow-up (CHAPTERS 2 and 3).
- Laparoscopic sacrohysteropexy and vaginal sacrospinous hysteropexy are comparable in their effectiveness for women with uterine prolapse, as we have shown with the results of a retrospective study and a randomised trial at one year follow-up. In both studies, there were no differences in overall anatomical recurrences and disease-specific quality of life (CHAPTERS 4 and 5).

- Laparoscopic sacrocolpopexy and vaginal sacrospinous fixation are both effective surgical treatment options at twelve months follow-up, in the treatment of vaginal vault prolapse. Although, there seems to be a clinically relevant difference in surgical reinterventions for the apical compartment in favour of the LSC (CHAPTERS 6 and 7).
- Preferred treatment options for vaginal vault prolapse differ amongst Dutch gynaecologists. Most important factors on which their decisions are based are whether it is a recurrent apical prolapse, patient's health status, and patient's own preference (CHAPTER 8).

### Scientific and societal impact

Mainly, two surgical routes can be utilised in the treatment of middle compartment prolapse; the vaginal route (vaginal sacrospinous fixation (VSF) for vaginal vault prolapse and vaginal sacrospinous hysteropexy (SSHP) for uterine descent) and the abdominal route (sacrocolpopexy and sacrohysteropexy).

The SALTO trial has confirmed the effectiveness of laparoscopic sacrocolpopexy (LSC) for vaginal vault prolapse, as it is as successful as the open abdominal technique (ASC) after short- and long-term follow-up. This minimally invasive procedure has already been widely implemented, but a prospective comparative trial with long-term follow-up was lacking. Also, this long-term follow-up of an RCT is an addition to the existing literature by presenting the clinical outcomes (disease-specific quality of life, anatomical results, bulge symptoms) as well as the long-term complications (mesh exposures) after LSC and ASC. Consequently, the ASC should no longer be performed, unless there is a specific reason to do so, *e.g.*, a technical issue or a complication which arises during the laparoscopy.

We conducted two other randomised controlled trials about the surgical treatment of apical prolapse and the results at 12 months follow-up were presented. The LAVA trial was the first RCT to compare LSH to SSHP in the treatment of uterine descent. The SALTO-2 trial is one of the first two RCTs to compare LSC to VSF for post-hysterectomy vaginal vault prolapse. Unique to both trials is that they have specifically defined inclusion criteria concerning uterine descent or post-hysterectomy vault prolapse. In previously published review articles, both women with and without a uterus were included and compared, which may affect the outcome of those reviews.<sup>7, 10</sup> These results are important to inform patients of what to expect after prolapse surgery. Based on these studies, there is not one surgical treatment favourable compared to the other. Although, in the SALTO-2 trial, there seems to be a clinically interesting difference in the number

of surgical reinterventions in favour of the LSC. When this finding is confirmed and indeed statistically significant after long-term follow-up, it is advisable to perform LSC in women who have a higher chance of recurrence.

It is known that POP recurrence or mesh complications can arise after many years. Therefore, reliable long-term results are also needed, and they are to be expected from our trials in a few years. Moreover, a meta-analysis of several RCTs including our trials should be performed in the nearby future to achieve the highest level of evidence and confirm the results of our studies by combining them with other evidence.

The results of our qualitative study show that gynaecologists who do not perform the sacrocolpopexy in their own clinic are more likely to perform a VSF and seem to find more reasons not to advise a sacrocolpopexy. On the other hand, patients from gynaecologists who do perform sacrocolpopexy in their clinics are perhaps more likely to undergo a treatment with mesh. This difference can partly be considered practice pattern variation (PPV). PPV is the variance in care which cannot be clarified by the specifics of the medical condition. PPV can lead to under- and overtreatment and therefore could introduce unnecessary risks of surgery, or patients might not receive adequate treatment for their medical condition.<sup>11, 12</sup> Our qualitative study can improve awareness of this issue and is relevant in order to develop plans and actions that can lead to reduce PPV. More research is needed to investigate which factors are truly of importance, so patients can get a personalised decision aid to make the choice between different treatment options. If PPV can be further reduced in the future, it could lead to less health care expenses, as PPV is associated with higher costs.<sup>11, 13</sup>

### **Activities leading to greater involvement**

In order to inform other health care workers, our data is published in peer-reviewed journals and presented at global and nationwide conferences. It can be used for review articles, meta-analyses, and guidelines. To enable this, we selected outcome measures that are similar to those in other trials (*e.g.*, combined outcome of success, anatomical failure, prolapse beyond the hymen, and disease-specific quality of life). For patients and health care professionals, guidelines are one of the most important outcomes in daily practice. The Dutch ‘Prolapse’ guideline dates from 2014 and is ready to be updated. Although some modules have been updated in recent years, more new studies can be added. The data presented in the guideline should be adjusted into personalised decision aids for patients.

Learning more about pelvic floor disorders (PFD), which includes POP, is very important for patients. Many women suffer from bothersome or functional symptoms, without

realising that the problem is very common and there are several treatment options available. There are numerous international and national resources that make an effort to inform women about the condition and the different treatment options. These include the patient leaflets from IUGA (many also available in Dutch),<sup>14</sup> several Dutch websites (*e.g.*, [www.bekkenbodem4all.nl](http://www.bekkenbodem4all.nl), [www.bekkenbodemwijzer.nl](http://www.bekkenbodemwijzer.nl), and [www.degynaecoloog.nl](http://www.degynaecoloog.nl))<sup>15-17</sup> and social media platforms (*e.g.*, Instagram).<sup>18</sup> This information is easily accessible for both doctors and patients. Moreover, it is especially important to empower women to search for their preferred personalised solution of POP. Even if their gynaecologist does not offer this specific treatment. Studies like ours can contribute to the content of the information and even more important to the knowledge of women.

### **Impact of this thesis**

In this thesis, the search for the most optimal treatment of apical prolapse has been expanded. It is clear that there is no longer a place for an intended open abdominal sacrocolpopexy. The LAVA trial and the SALTO-2 trial show no superior surgical technique in the treatment of uterine descent or vaginal vault prolapse, respectively. Until further evidence is published, all techniques can be used in the treatment of apical prolapse, provided that the patient made a fully informed decision.

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