A randomised trial comparing open Burch colposuspension using sutures with laparoscopic colposuspension using mesh and staples in women with stress urinary incontinence

Maud Ankardal, Anne Ekerydh, Kristina Crafoord, Ian Milsom, Jan-Henrik Stjerndahl, Marie Ellström Engh

Objective To compare open Burch colposuspension using sutures with laparoscopic colposuspension using mesh and staples in women with stress urinary incontinence.

Design Multicentre, prospective randomised trial.

Setting Departments of Obstetrics and Gynaecology, Sahlgrenska University Hospital, Göteborg, Borås County Hospital and Örebro University Hospital, Sweden.

Population Women with genuine stress urinary incontinence or mixed incontinence with a predominantly stress component were included, and were randomised to either open colposuspension (n = 120) or laparoscopic colposuspension (n = 120).

Methods Women were randomised to open colposuspension with sutures or laparoscopic colposuspension with polypropylene mesh and staples. Anaesthesia/operation time, blood loss, complications and other related surgical parameters were compared.

Main outcome measures Objective and subjective cure rates from 48-hour frequency–volume chart, a 48-hour pad test and a subjective assessment of the woman’s incontinence and quality of life performed one year after surgery.

Results Objective and subjective cure rates were higher after open compared with laparoscopic colposuspension (P < 0.001). Quality of life was improved following surgery in both groups (P < 0.0001) and the improvement was significantly greater in the open colposuspension group (P < 0.05) with regard to physical activity. Performing an open colposuspension was less time consuming (P < 0.0001), resulted in more blood loss (P < 0.0001), longer catheterisation time (P < 0.01), greater risk of urinary retention (P < 0.01) and a longer hospital stay (P < 0.0001) compared with performing a laparoscopic colposuspension. The rate of serious complications was low in both groups.

Conclusion Open colposuspension had a higher objective and subjective cure rate one year after surgery but with a greater blood loss, greater risk of urinary retention and a longer hospital stay than laparoscopic colposuspension.

INTRODUCTION

The use of minimal invasive surgery has increased during the last 10 years and the laparoscopic approach is used routinely for many gynaecological procedures. The advantages with the laparoscopic technique are allegedly less pain, and shorter hospitalisation and convalescence. The laparoscopic approach has also been introduced into incontinence surgery, where several different techniques have been described as an alternative to the gold standard of Burch colposuspension. Randomised trials have been undertaken comparing open and laparoscopic colposuspension with conflicting results. Most of these studies have compared laparoscopic colposuspension using sutures with open colposuspension. In 1993, a laparoscopic technique was introduced where sutures were replaced with mesh and staples. This technique was suggested to simplify the procedure, making it faster and more accessible to surgeons with less training in laparoscopic surgery. The aim of this study was to perform a randomised trial comparing open colposuspension using sutures with laparoscopic colposuspension using mesh and staples.

METHODS

This trial was performed at the Departments of Obstetrics and Gynaecology, Sahlgrenska University Hospital, Göteborg, Borås County Hospital and the University Hospital in Örebro, Sweden. The study was approved by the local Ethics Committee.

All incontinent women referred to the incontinence units at these centres during the period 1996 to 2000 underwent a standardised assessment. Patients thought to have genuine stress incontinence or mixed incontinence with a predominately stress component were offered participation in the study. Patients with recurrent incontinence, or where additional gynaecological surgery which might affect cure rate was planned simultaneously, were excluded. Four patients who had posterior colporrhaphy and four who had adnexal surgery were included. Each patient was given written information before being enrolled in the study. Opaque sealed envelopes were distributed to the different centres before starting the randomisation. The patients were randomly allocated to either colposuspension using sutures with the open technique, open colposuspension ($n=120$) or colposuspension using mesh and staples with laparoscopic technique ($n=120$). A CONSORT flow diagram$^9$ is shown in Fig. 1. Twenty-two patients randomised to open colposuspension and 11 patients randomised to laparoscopic colposuspension were excluded prior to surgery when later found not to fulfil the inclusion/exclusion criteria or because they regretted their earlier decision to participate and therefore declined surgery. Thus, 98 women in the open colposuspension group and 109 women in the laparoscopic colposuspension group underwent surgery and were included in the analyses. Five patients randomised to laparoscopic colposuspension were converted to open surgery: in two cases open surgery was performed after bladder perforation and in three cases the procedure was converted due to anaesthetic complications. One patient in the open colposuspension group and four patients in the laparoscopic colposuspension group were not available for the follow-up one year after surgery and thus 97 women randomised to open colposuspension and 105 women randomised to laparoscopic colposuspension were available for evaluation at the one year follow up.

An objective assessment of the woman’s incontinence was performed pre-operatively using a self-completed 48-hour frequency–volume ($F/V$) chart to exclude women with extremely large 24-hour urinary volumes, and women with small mean micturated volumes as a sign of an urge component. A 48-hour pad test was also performed. The women were requested to indicate whether or not they had urinary incontinence and in which situations leakage occurred. When this study was planned no validated quality of life incontinence questionnaire translated into Swedish was available. Thus, a subjective assessment of all patients was performed using a questionnaire (Appendix A) containing a series of visual analogue scales (VAS) measuring the impact (bothersomeness) incontinence had on different aspects of quality of life (zero value corresponding to no problems and 100 value to a maximum of bother). A gynaecological examination including assessment of vaginal descent was also performed.

Senior surgeons with long experience of incontinence surgery performed all procedures. The laparoscopic procedure was introduced at the centres two years before initiating the study. During that period the incontinence surgeons ($n=7$) with most laparoscopic training performed more than 60 laparoscopic colposuspension procedures. During the study period, another two senior surgeons were introduced and performed the procedure under the guidance of the more experienced colleagues.

Open Burch colposuspension was performed through a Pfannenstiel incision or through any previous lower midline incision. The anterior peritoneum was dissected away from the anterior abdominal wall and the space of Retzius was entered between the symphysis pubis and the anterior surface of the bladder and the urethra. With a finger in the vagina elevating the anterior vaginal wall, the bladder base was dissected bluntly and pushed medially. Two sutures were inserted into the paravaginal fascia approximately 2 cm lateral to the urethra and 2 cm distal to the bladder neck and the nearest point on the ipsilateral Cooper’s ligament, thereby approximating the paravaginal fascia. A number 0 non-resorbable polybutylated-coated polyester suture was used (Surgidac, Tyco Healthcare Norden, Gårdsvägen 14 169 70 Solna, Sweden). The procedure was repeated on the contralateral side. A suprapubic catheter was introduced for post-operative drainage and was removed post-operatively when the patient had <150 mL in residual volume.

Colposuspension with the laparoscopic technique was performed using the transperitoneal approach. In addition to the 11-mm umbilical cannula for the laparoscope, two 5-mm working ports were inserted lateral to the rectus muscle between the symphysis pubis and the umbilicus. One 11-mm port was inserted centrally between the symphysis pubis and the umbilicus. The bladder was filled with 300 mL of blue-stained normal saline (3 mL methylene blue 10 µg/mL in 1000 mL normal saline) facilitating the identification of the upper limit of the bladder. Thereafter, the anterior peritoneum was incised into the space of Retzius. The bladder was emptied and the dissection of the paravaginal fascia was done using the same technique as in open surgery. A polypropylene mesh ($1 \times 5$ cm, Prolene, Johnson and Johnson, Sollentuna, Sweden) and 3–4 titan staples ($5.3 \times 3.7$ mm, EMS Endopath Stapler Multifeed, Johnson and Johnson) were used to approximate the paravaginal fascia to Cooper’s ligament on each side. The space of Retzius was left open. The indwelling catheter used to fill the bladder during the operation was left in situ and removed the day after surgery. The residual urine volume was then checked by ultrasound, until it was <150 mL. All patients were given antibiotic prophylaxis.

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Assessed for eligibility, $n \approx 720$

Excluded, $n \approx 480$
- Did not fulfill inclusion/exclusion criteria.
- Unwilling to participate in a randomised controlled trial

Randomised, $n = 240$

Allocated to Open Colposuspension, $n = 120$
- Underwent open colposuspension, $n = 98$
  - Not operated, $n = 22$
    (Did not meet inclusion criteria or regretted their decision and declined surgery after randomisation)

Allocated to Laparoscopic Colposuspension, $n = 120$
- Underwent laparoscopic, $n = 109$
  - Not operated, $n = 11$
    (Did not meet inclusion criteria or regretted their decision and declined surgery after randomisation)

Converted to open colposuspension, $n = 5$

Lost to follow-up, $n = 1$

Analysed, $n = 97$
- Some women did not complete all assessments, resulting in different figures for the numbers evaluated
  - Objective cure, $n = 91$
  - Subjective cure, $n = 95$
  - Bother (VAS), $n = 91$
  - QoL physical activity, $n = 84$
  - QoL work, $n = 77$
  - QoL social life, $n = 84$
  - QoL sex, $n = 77$

Lost to follow-up, $n = 4$

Analysed, $n = 105$
- Some women did not complete all assessments, resulting in different figures for the numbers evaluated
  - Objective cure, $n = 96$
  - Subjective cure, $n = 104$
  - Bother (VAS), $n = 98$
  - QoL physical activity, $n = 96$
  - QoL work, $n = 91$
  - QoL social life, $n = 97$
  - QoL sex, $n = 90$

Fig. 1. Flow diagram of subjects progress through the phases of this randomised trial.

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pre-operatively, using cefuroxime 1.5 g × 3 and metronidazole 1.5 g × 1 intravenously, followed by cefadroxil 1 g × 2 per-orally the first post-operative day.

The operating time for the procedure was defined as the time from the skin incision to the time when the last skin suture was placed and included the introduction of the suprapubic catheter in the open colposuspension group. Blood loss was estimated by the anaesthetic personnel and by comparing pre-operative haemoglobin concentration with values obtained the first post-operative day. Any blood transfusion was recorded. The number of days with indwelling or suprapubic catheter left in situ was registered.

The patients were discharged from hospital with or without a catheter when feeling physically fit and not requiring opioid analgesics. The number of post-operative nights spent in the hospital was noted. No attempt to mask the type of procedure to the staff at the ward was made. Patients in both groups were recommended six weeks sick leave if not retired. They were instructed to avoid lifting, heavy exercise and intercourse during convalescence. The patients were examined four to six weeks post-operatively by clinical examination and confirmed by ultrasound. One urinary culture. Post-operative haematomas were diagnosed by clinical signs and confirmed by ultrasound. One year post-operatively the women were assessed by one of the authors and a urotherapist at each of the participating centres. The same assessments (48-hour F/V chart and 48-hour pad test) performed pre-operatively were repeated (objective cure was defined as a urinary leakage <8 g/24 hours according to a 48-hour pad test). The women were questioned whether or not they had urinary leakage and other forms of voiding dysfunction. The women were assessed subjectively in the same manner as pre-operatively using the questionnaire (Appendix A) assessing quality of life. The woman’s degree of overall satisfaction regarding the result of the operation was also estimated using a VAS scale (zero value corresponding to the lowest degree of satisfaction and 100 value corresponding to maximum satisfaction). The patient was also asked if she would recommend the procedure to another woman with similar complaints.

The number of patients to be included (120 vs 120) was calculated in order to detect a statistically significant difference of 15% between open colposuspension and laparoscopic colposuspension with a power >80% if the expected cure rate of an open colposuspension was 90%. The statistical analyses were performed in the 98 women who underwent open colposuspension and the 109 women who underwent laparoscopic colposuspension. With this reduced number of patients it was still possible to detect a statistically significant difference of 15% between open colposuspension and laparoscopic colposuspension with a power of 80%. Data were expressed as means (standard deviation, SD). Comparison between groups was made using t test, Fisher’s exact test and Wilcoxon rank sum test. Analysis was performed on an intention-to-treat basis.

RESULTS

The patient characteristics were the same in both groups (Table 1). The objective cure rate, subjective cure and subjective improvement rate reported one year after surgery

Table 1. Patient characteristics [mean value (SD)].

<table>
<thead>
<tr>
<th></th>
<th>Open colposuspension (n = 98)</th>
<th>Laparoscopic colposuspension (n = 109)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (year)</td>
<td>42.6 (31.2)</td>
<td>40.9 (31.1)</td>
</tr>
<tr>
<td>Body mass index</td>
<td>25.7 (3.6)</td>
<td>25.0 (3.3)</td>
</tr>
<tr>
<td>Parity</td>
<td>2.3 (1.1)</td>
<td>2.3 (1.1)</td>
</tr>
<tr>
<td>Postmenopausal (%)</td>
<td>46</td>
<td>53</td>
</tr>
<tr>
<td>Oestrogen therapy (%)</td>
<td>50</td>
<td>48</td>
</tr>
<tr>
<td>Leakage at Pad-test (g/24 hours)</td>
<td>137 (206)</td>
<td>108 (175)</td>
</tr>
<tr>
<td>Mean micturated volume (mL)</td>
<td>267 (108)</td>
<td>252 (91)</td>
</tr>
</tbody>
</table>

Table 2. Objective and subjective results one year after surgery. Values are presented as n/N (%).

<table>
<thead>
<tr>
<th></th>
<th>Open colposuspension</th>
<th>Laparoscopic colposuspension</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leakage &lt;8 g/24 hours at 48-hour Pad-test</td>
<td>84/91 (92)</td>
<td>71/96 (74)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Subjectively dry (questioned by study nurse)</td>
<td>85/95 (89)</td>
<td>64/104 (62)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Open colposuspension</th>
<th>Laparoscopic colposuspension</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bother due to urinary leakage*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No leakage, no bother</td>
<td>52/91 (57)</td>
<td>26/98 (27)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Improvement in VAS score</td>
<td>37/91 (41)</td>
<td>62/98 (63)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>No improvement or worse</td>
<td>2/91 (2)</td>
<td>10/98 (10)</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

N = number of patients evaluated, n = number of patients cured or improved.

* According to VAS questionnaire.

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was significantly higher in the open colposuspension group compared with the laparoscopic colposuspension group (Table 2). Quality of life, assessed by a visual analogue scale, was improved in all domains following surgery in both groups (typically, $P < 0.0001$) (Table 3). The improvement was greater ($P < 0.05$) in the open colposuspension group with regard to physical activity following surgery. The overall satisfaction rate (assessed by VAS) was higher in the open colposuspension group compared with the laparoscopic colposuspension group [open colposuspension: 91 (20) mm; laparoscopic colposuspension: 73 (34) mm; $P < 0.0001$]. More patients in the open colposuspension group compared with patients in the laparoscopic colposuspension group indicated that they would recommend the procedure to another woman with similar complaints (open colposuspension 90% vs laparoscopic colposuspension 79%; $P < 0.05$).

Performing an open colposuspension was less time consuming, resulted in more blood loss, longer use of a catheter and a longer hospital stay compared with performing a laparoscopic colposuspension (Table 4). All complications that occurred are shown in Table 5. No significant differences were noted except for days of urinary retention.

**DISCUSSION**

This study has demonstrated a higher cure rate after open Burch colposuspension compared with the modified laparoscopic colposuspension with mesh and staples. This conclusion was reflected in both subjective and objective parameters. Quality of life, assessed by a visual analogue scale, was improved following surgery in both groups and was significantly better in the open colposuspension group with regard to physical activity following surgery.

As far as we are aware, there is only one other randomised prospective study comparing open colposuspension with a laparoscopic mesh technique and the results of this study are in line with our findings. The authors used tackers instead of staples. Data from two non-randomised studies, including the first report of the technique, disagree with our

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**Table 3.** Improvement in the impact of incontinence on different aspects of quality of life (QoL) one year after surgery measured by a VAS score. Zero value corresponding to no problems and 100 to a maximum of bother. Data are median (range). Differences between pre-operative scores and one-year scores were highly significant in both groups for each domain (typically, $P < 0.0001$).

<table>
<thead>
<tr>
<th></th>
<th>Physical activity</th>
<th>Working ability</th>
<th>Social life</th>
<th>Sexual life</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$N$</td>
<td>Open colposuspension</td>
<td>$N$</td>
<td>Laparoscopic colposuspension</td>
</tr>
<tr>
<td>Before treatment</td>
<td></td>
<td>80 (60–90)</td>
<td>80 (67–91)</td>
<td></td>
</tr>
<tr>
<td>One year post-operatively</td>
<td>0 (0–4)</td>
<td>0 (0–47)</td>
<td>1 (0–47)</td>
<td></td>
</tr>
<tr>
<td>Difference</td>
<td>84</td>
<td>74 (52–84)</td>
<td>96</td>
<td>63 (27–81)</td>
</tr>
<tr>
<td>$P^*$</td>
<td></td>
<td></td>
<td>38 (10–60)</td>
<td>41 (14–67)</td>
</tr>
<tr>
<td>Before treatment</td>
<td></td>
<td>0 (0–0)</td>
<td>0 (0–13)</td>
<td></td>
</tr>
<tr>
<td>One year post-operatively</td>
<td>31 (10–60)</td>
<td>25 (4–54)</td>
<td>97</td>
<td>37 (15–66)</td>
</tr>
<tr>
<td>Difference</td>
<td>77</td>
<td>38 (10–65)</td>
<td>90</td>
<td>13 (1–41)</td>
</tr>
<tr>
<td>$P^*$</td>
<td></td>
<td></td>
<td>19 (2–49)</td>
<td>21 (6–72)</td>
</tr>
<tr>
<td>Before treatment</td>
<td></td>
<td>0 (0–0)</td>
<td>0 (0–10)</td>
<td></td>
</tr>
<tr>
<td>One year post-operatively</td>
<td>9 (0–37)</td>
<td>13 (1–41)</td>
<td>90</td>
<td>13 (1–41)</td>
</tr>
<tr>
<td>Difference</td>
<td>77</td>
<td>9 (0–37)</td>
<td>90</td>
<td>13 (1–41)</td>
</tr>
</tbody>
</table>

$^*$ Comparison between groups.

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**Table 4.** Per-operative and post-operative data [mean value (SD)].

<table>
<thead>
<tr>
<th></th>
<th>Open colposuspension ($n = 98$)</th>
<th>Laparoscopic colposuspension ($n = 109$)</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time of anaesthesia (minutes)</td>
<td>106 (27)</td>
<td>123 (30)</td>
<td>$&lt;0.0001$</td>
</tr>
<tr>
<td>Time of surgery (minutes)</td>
<td>60 (19)</td>
<td>75 (24)</td>
<td>$&lt;0.0001$</td>
</tr>
<tr>
<td>Estimated blood loss (mL)</td>
<td>105 (99)</td>
<td>35 (101)</td>
<td>$&lt;0.0001$</td>
</tr>
<tr>
<td>Reduction in haemoglobin (mg/L)</td>
<td>17 (15)</td>
<td>10 (13)</td>
<td>$&lt;0.01$</td>
</tr>
<tr>
<td>Duration of bladder drainage (days)</td>
<td>4.9 (8.3)</td>
<td>1.9 (2.4)</td>
<td>$&lt;0.01$</td>
</tr>
<tr>
<td>Duration of hospital stay (nights)</td>
<td>3.9 (1.5)</td>
<td>2.2 (1.3)</td>
<td>$&lt;0.0001$</td>
</tr>
</tbody>
</table>

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findings.\(^2\)\(^1\) The latter was a retrospective study using historical controls and showed no difference between the open Burch colposuspension and a laparoscopic technique with mesh and staples.\(^1\)\(^1\)

In a Cochrane review of laparoscopic colposuspension,\(^1\)\(^2\) almost all randomised studies analysed used a suturing technique to suspend the vagina. Four trials of good quality comparing open and laparoscopic colposuspension using sutures were found.\(^6\)\(^–\)\(^8\),\(^1\)\(^3\) These four studies included 144 women undergoing laparoscopic colposuspension and 208 women undergoing open colposuspension. No significant difference between the two techniques was shown but the authors implied that the long term performance might be worse for the laparoscopic approach. The only study evaluating mesh in this report was found to have too small a sample size to be conclusive.\(^1\)\(^4\) Recently, more data concerning the simplified technique using mesh have emerged.\(^1\)\(^1\)\(^1\) There is only one prospective randomised study comparing laparoscopic suturing with laparoscopic mesh and staples and this study showed the same decline in success rate, one year after surgery, in the mesh/staples group\(^3\) as shown in our trial.

The present study was a randomised controlled trial where 207 women underwent surgery. Several women who were randomised did not undergo surgery. We have no reason to believe that the withdrawal of these patients generated bias and we do not consider this influenced the outcome. Despite the missing data, a sufficient number of women completed the study to satisfy the statistical power requirements. In this study, using the open technique and suspending the vagina with sutures resulted in a better outcome. However, these patients had more problems with voiding after surgery and a longer stay in hospital, suggesting that suturing results in a higher suspension of the vagina. The risk of overcorrecting the vaginal position might be greater when using sutures compared with staples and mesh. Another explanation might be that fixation of the vagina with staples is less successful compared with sutures. In our experience, this is indeed the case (unpublished data). In the present study, it was not possible to determine whether or not the reported outcome was influenced by the choice of surgical approach (i.e. open or laparoscopic technique) or by the way in which the vagina was suspended (mesh/staples or sutures). This reflects the need for future randomised controlled trials comparing different ways of suspension, sutures or mesh and staples/tackers with the same surgical approach.

CONCLUSION

Open colposuspension had a higher objective and subjective cure rate one year after surgery compared with laparoscopic colposuspension with mesh and staples. Open colposuspension was associated with a greater blood loss, greater risk of urinary retention and a longer hospital stay than laparoscopic colposuspension.

Acknowledgements

The authors would like to thank the participation of Dr Margaretha Åkeson and Dr Karin Franzaén in this study and Björn Areskoug BSc for assistance with the statistical analysis. The study was supported by grants from the Swedish Medical Research Council (B95-17X-11237-01A), the Göteborg Medical Society Fund.

References

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Appendix A.

The aim of the questions below is to assess your urinary incontinence and urge symptoms and the impact of these symptoms on your daily life in different situations. Below you will find a 100 mm long line. The one extremity of this line represents e.g. no problem at all with the symptom under evaluation. The other end of the line represents the other extreme, intolerable bother as a result of this symptom. Please mark on the line your own assessment of your symptom regarding the degree of bother from none at all to intolerable. If you do not suffer from this symptom at all mark the box indicated.

A: Urinary leakage

0 [ ] [ ] 100

No problem Intolerable situation

I have no urinary leakage [ ]

B: Urinary urge

0 [ ] [ ] 100

No problem Intolerable situation

I have no urinary urge [ ]

If you have no urinary leakage or urinary urge you can go to question G

C: Urinary leakage affects my physical activity, e.g. aerobics, exercise, gardening, shopping

0 [ ] [ ] 100

No influence at all Makes it impossible

D: Urinary leakage affects my work…

0 [ ] [ ] 100

No influence at all Makes it impossible

E: Urinary leakage affects my social life outside work e.g. friends, hobbies, cinema…

0 [ ] [ ] 100

No influence at all Makes it impossible

F: Urinary leakage affects my sexual life

0 [ ] [ ] 100

No influence at all Makes it impossible

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The following questions were asked at the postoperative assessment only

G: Compared to the situation before the operation my leakage is

\[
\begin{align*}
0 \quad & \quad 100 \\
\text{None existent} & \quad \text{Much worse}
\end{align*}
\]

H: If You had urge-problems before the operation, answer the following question:

Compared to the situation before the operation urinary urge is

\[
\begin{align*}
0 \quad & \quad 100 \\
\text{None existent} & \quad \text{Much worse}
\end{align*}
\]

I: My overall opinion regarding the result of the operation

\[
\begin{align*}
0 \quad & \quad 100 \\
\text{Very dissatisfied} & \quad \text{Very satisfied}
\end{align*}
\]

J: Would You recommend the operation to others with equal problems…

Yes  ☐

No  ☐

Do not know  ☐