ORIGINAL ARTICLE

Evaluation of suture material used in anterior colporrhaphy and the risk of recurrence

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Abstract

Introduction and hypothesis The wide variety of suture material used in colporrhaphy shows a lack of consensus on the optimal choice. The evidence guiding the choice of suture material is scant. The aim of this study was to investigate the effects of rapid versus slowly absorbable suture on risk of recurrence after native tissue anterior colporrhaphy.
Methods This longitudinal cohort study was performed secondary to a previously published study on pelvic organ prolapse recurrence after the Manchester-Fothergill procedure versus vaginal hysterectomy. Data were collected from four Danish databases and corresponding electronic medical records. In this study, women having had anterior colporrhaphy performed were included. Suture materials were divided in three groups: rapid absorbable multifilament suture (RAMuS), rapid absorbable monofilament suture (RAMoS) and slowly absorbable monofilament suture (SAMoS). The main outcome was recurrence of prolapse in the anterior compartment.
Results A total of 462 women were included in this study. No significant difference in recurrence was found among the three suture groups. However, a non-significant tendency towards a higher risk of recurrence in the RAMoS group [HR 2.14 (0.75–6.10) $p = 0.16$] compared to the RAMuS group was observed.
Conclusion In this study, the use of rapid absorbable multifilament suture compared to slowly absorbable monofilament suture does not seem to lead to a higher risk of recurrence after anterior colporrhaphy.

Keywords Anterior colporrhaphy · Pelvic organ prolapse · Recurrence · Suture material · Suture technique

Introduction

The lifetime risk for pelvic organ prolapse (POP) surgery in Denmark is 18.7% [1]. The anterior vaginal wall is the most typical compartment for a vaginal prolapse [2, 3], and the most common surgical treatment for prolapse in the anterior compartment is colporrhaphy [4, 5]. It is well known that the recurrence rate after anterior colporrhaphy is high; up to 65% has been documented in the literature [6]. Furthermore,

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a Danish cohort study found a reoperation rate of 12.4% in the anterior compartment [7].

Clearly, it is important to identify surgical variables that can improve the procedure and minimize the rates of recurrences and reoperations. The wide variety of suture material used in this procedure shows a lack of consensus on the optimal choice.

Anterior native tissue colporrhaphy is performed with a midline plication of the fascia [4]. Scientific evidence guiding the choice of suture material and suture technique for this procedure is scant. The use of mesh has been investigated, where a slightly better anatomical recurrence rate after the use of mesh compared to native tissue repair has been found, but at the cost of a higher risk of complications [6]. To our knowledge, only one small randomized clinical trial [8, 9] and one register study [10] have been conducted on the choice of suture material in anterior colporrhaphy.

However, in the field of abdominal surgery, the importance of suture material and technique has been thoroughly studied. The European Hernia Society guidelines on the closure of

abdominal wall incisions recommend using continuous suture with slowly absorbable monofilament material for midline closure of the fascia [11].

Studies regarding the texture of sutures have shown that multifilament sutures induce a more intense inflammatory response and larger spread of microorganisms compared to monofilament sutures [12]. A study on vaginal closure in POP surgery has shown an increased risk of vaginal discharge after use of multifilament compared to monofilament suture [13].

Our hypothesis was that the use of slowly absorbable monofilament suture is associated with a lower risk of recurrence in native tissue anterior colporrhaphy than the use of rapid absorbable multifilament suture.

The aim of this study was to investigate the effects of rapid versus slowly absorbable suture on risk of recurrence after native tissue anterior colporrhaphy.

Method

Data sources

This longitudinal cohort study is performed secondary to a previously published study on POP recurrence and clinical outcomes after the Manchester-Fothergill procedure (MP) and vaginal hysterectomy (VH) [14]. Data were collected from four Danish databases and corresponding electronic medical records. Data from these databases were merged using the unique personal identification number in the Danish Civil Registration System. The electronic medical records were read through manually. The four databases included the Danish Urogynecological Database, Danish Anaesthesia Database, Danish Hysterectomy and Hysteroscopy Database and Danish National Pathology Registry and Danish National Data Bank. In Denmark, reporting to all databases is mandatory, which ensures high data completeness [15–17]. In this study, the description of surgical procedures from electronic medical records was read through again by one single author, and data on suture material and suture technique were collected.

Variables and main outcome

The suture material used in anterior colporraphy was divided into groups based on the strength and texture of the suture. Sutures where the strength was half of the initial strength at $\leq$ 3 weeks were categorized as rapidly absorbable and sutures where the strength was more than half of the initial strength at 3 weeks were categorized as slowly absorbable sutures. The multifilament sutures had a strength of half the initial strength at 3 weeks; therefore, the same categorisation of monofilament sutures was made. The sutures were also divided into

groups based on whether they were multi- or monofilament. There were no slowly absorbable multifilament sutures; thus, three groups were made: rapidly absorbable multifilament sutures (RAMuS) including Vicryl® and Polysorb®, rapidly absorbable monofilament sutures (RAMoS) including Biosyn® and one group of slowly absorbable monofilament sutures (SAMoS) including PDS® and Monomax® (Table 3). Cases where both slowly and rapidly absorbable sutures were used were categorized as slowly absorbable sutures. In cases where both types of sutures were used, continous slowly absorbable monofilament sutures were used in the first layer of the fascia followed by single rapidly absorbable sutures in the second layer. Suture technique was noted in two groups: one layer of suture or two layers of suture.

The main outcome was recurrence of POP in the anterior compartment. Recurrence was defined as one or more of the following: POP treated with pessary or surgery, POP-Q stage 2 with POP symptoms or POP-Q stage $\geq$ 3 independent of POP symptoms.

Study population

In the primary study, women with a prolapse in the apical compartment who had either VH or MP done were included. This resulted in a matched cohort of 295 pairs, a total of 590 women. Operations were performed between 2010 and 2014 (both inclusive) at four public university hospitals with a specialized urogynaecology unit in the Capital region. The follow-up time was from 20 to 48 months [14].

In this study, women were included if they had an anterior colporrhaphy performed in addition to the VH/MP-operation and if information on the suture material used during surgery was available.

Ethics and statistics

Statistical analyses were performed with SAS version 7.1 (SAS Institute, Cary, NC, USA).

Baseline characteristics are presented as total number (%) for categorical variables or median (q1–q3) for continuous variables. For comparison of baseline characteristics between groups, the Wilcoxon rank sum test was performed for continuous nonparametric variables. Fisher's exact test or chi-squared test was performed for categorical variables.

Data were analysed with the Cox proportional hazard ratio using univariate and multivariate analyses. Variables with $p < 0.1$ in the univariate analyses were included in the multivariate analysis. The assumptions for using proportional hazards were analysed with Wald test with a time-dependent covariate and the Schoenfeld residual plots.

A $p < 0.05$ was considered statistically significant for all comparisons.

The Danish Health and Medicines authority approved acquisition of data from patient records (3–3013-1397/1 and 3–3013-1397/2). The storage of data was approved by the Danish Data Protection Agency (2012–58-0004).
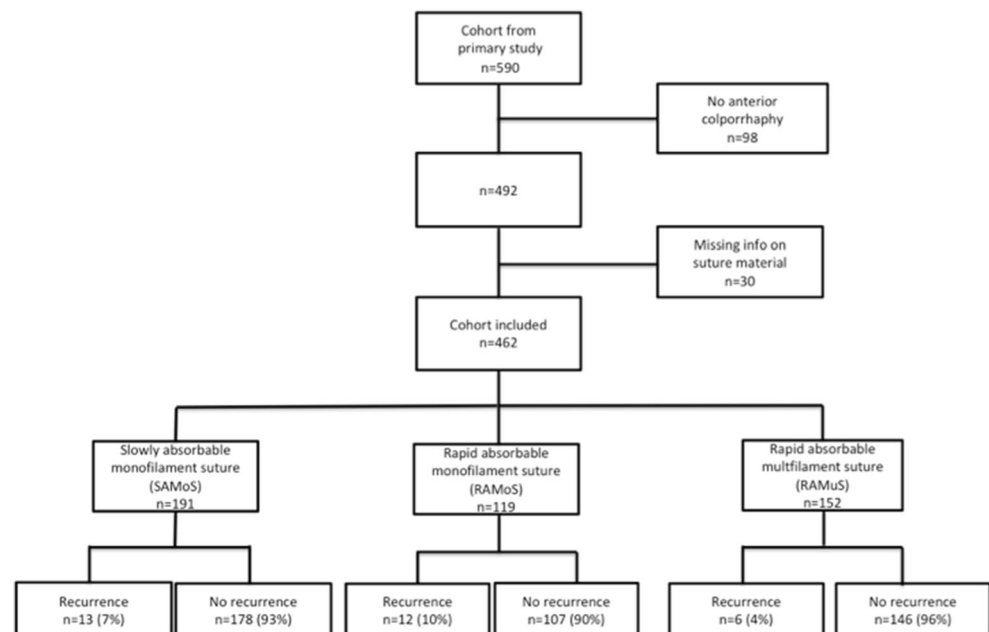
Results

Demographics

Of the 590 women included in the primary matched cohort study [14], 462 underwent colporraphy and were included in this study. SAMoS was used in anterior colporrhaphy in 191 (41%) women, RAMoS in 119 (26%) and RAMuS in 152 (33%) (Fig. 1).

The groups were comparable on several baseline characteristics, including parity, caesarean section, age and body mass index. However, they differed on some of the parameters (Table 1). The group sutured with SAMoS underwent surgery by more experienced surgeons compared to RAMuS and RAMoS and had a higher POP-Q-stage in both the anterior and apical compartment and more smokers than the RAMoS group. The group sutured with RAMuS more often had MP as concomitant surgery and two layers of sutures compared to the SAMoS and RAMoS groups. Furthermore, previous anterior colporrhaphy was more common in the RAMuS group compared to the SAMoS group. The group where RAMoS was used had a lower ASA score than the SAMoS and RAMuS groups and there were more postmenopausal women compared to the RAMuS group.

Suture material

No significant difference in recurrence was found among the three suture groups. However, a non-significant tendency towards a higher risk of recurrence in the RAMoS group [HR 2.14 (0.75–6.10) $p = 0.16$; Table 2] compared to the RAMuS group was observed in the Cox proportional hazard analysis and in the Kaplan-Meier plot (Fig.2).

Other variables and recurrence

For the POP-Q stage of anterior prolapse, we observed a tendency towards higher risk of recurrence in the women with stage 3–4 compared with the women with stage 0–2 (HR 1.94; 95% CI (0.86–4.37), $p = 0.11$), though these differences were not significant (Table 2).

There was no difference in risk of recurrence between the groups in the univariate analyses for variables of one or two layers of suture, previous anterior colporrhaphy and surgeon experience.

Discussion

Suture material

No significant difference in the risk of recurrence was found among the three suture groups in native tissue anterior colporrhaphy. Since the rapid absorbable multifilament suture had the lowest observed recurrence rate, the probability that this type of suture will lead to a higher risk of recurrence is small. However, a non-significant tendency of rapid

Fig. 1 Flow chart of inclusion, division and recurrence rate

absorbable multifilament suture being superior to rapid absorbable monofilament suture was found.

A previous Swedish register study published in 2016 found that the use of slowly absorbable suture decreases the odds of having symptomatic recurrence after an anterior colporrhaphy compared to the use of rapidly absorbable suture. Their main outcome was based on data collected with a 1-year follow-up questionnaire, in which the patients reported whether they had

Table 1 Baseline characteristics of the 462 women in the anterior colporrhaphy cohort

Characteristic	n	SAMos	RAMus	RAMoS
n	462	191	152	119
Concomitant surgical procedure	462			
Manchester-Fothergill Procedure (MP)		90 (47%)[0]*	110 (72%)[0]†	28 (24%)*†
Vaginal hysterectomy (VH)		101 (53%)[0]*	42 (28%)[0]†	91 (76%)*†
Number of layers of suture	462			
1		161 (84%)[0]	96 (63%)[0]†	108 (91%)†
2		30 (16%)[0]	56 (37%)[0]†	11 (9%)†
Previous anterior colporrhaphy.	462			
No		187 (98%) [0]	140 (92%) [0]	115 (97%)
Yes		4 (2%) [0]	12 (8%) [0]	4 (3%)
Previous posterior colporrhaphy.	462			
No		185 (97%)	146 (96%)	115 (97%)
Yes		6 (3%)	6 (4%)	4 (3%)
Surgeon experience level with MP/VH	457			
≤ 100		35 (18%)[0]*	8 (5%) [0]	12 (10%)*
> 100		155 (82%) [0]*	140 (95%)[0]	107 (90%)*
Current smoker	431			
No		154 (86%)*	126 (88%)	100 (93%)*
Yes		26 (14%)*	18 (12%)	7 (7%)*
Caesarean section(s)	430			
No		167 (92%)	126 (93%)	101 (89%)
Yes		14 (8%)	9 (7%)	13 (11%)
Menopause status	286			
Premenopausal		23 (20%)	25 (25%)†	8 (12%)†
Postmenopausal		89 (77%)	75 (74%)†	60 (88%)†
Perimenopausal		4 (3%)	2 (2%)	0
Preoperative POP-Q stage anterior compartment	461			
0–2		66 (35%)*	65 (43%)	56 (47%)*
3–4		125 (65%)*	86 (57%)	63 (53%)*
Preoperative POP-Q stage apical compartment	462			
0–2		135 (71%)*	102 (67%)†	103 (87%)*†
3–4		56 (29%)*	50 (33%)†	16 (13%)*†
Median age (q1–q3)	462	65 (51–71)	62 (51–70)	63 (55–69)
Median BMI (q1–q3)	444	25.0 (23.0–27.0)	25.2 (22.7–28.2)	24.7 (22.6–27.7)
Median parity (q1–q3)	447	2 (2–3)	2 (2–3)	2 (2–3)
Median ASA score (q1–q3)	455	2 (1–2) [0]*	2 (1–2)[0]†	1 (1–2)*†

SAMoS, slowly absorbable monofilament suture; RAMuS, rapid absorbable multifilament suture; RAMoS, rapid absorbable monofilament suture

[0] Significant difference between SAMoS and RAMuS ($p < 0.05$)

*Significant difference between RAMoS and SAMoS ($p < 0.05$)

†Significant difference between RAMoS and RAMuS ($p < 0.05$)

Table 2 Univariate and multivariate analyses of recurrence in the anterior compartment using the Cox proportional hazards ratio (*n* = 462)

Parameter	n	Hazard ratio (95% CI) univariate	p value	Hazard ratio (95% CI) multivariate*	p value
Suture material anterior colporraphy					
RAMuS	152	1.00 (ref)		1.00 (ref)	
SAMoS	191	1.83 (0.70–4.83)	0.22	1.54 (0.57–4.16)	0.39
RAMoS	119	2.59 (0.97–6.89)	0.057	2.14 (0.75–6.10)	0.16
Concomitant operation					
Manchester-Fothergill Procedure	228	1.00 (ref)		1.00 (ref)	
Vaginal hysterectomy	234	2.03 (0.96–4.31)	0.065	1.55 (0.69–3.48)	0.29
Preoperative POP-Q stage anterior compartment					
0–2	187	1.00 (ref)		1.00 (ref)	
3–4	274	1.98 (0.89–4.43)	0.095	1.94 (0.86–4.37)	0.11
Number of layers of suture					
2	97	1.00 (ref)		–	
1	365	1.06 (0.43–2.57)	0.90	–	–
Previous anterior colporrhaphy					
Yes	20	1.00 (ref)		–	
No	442	1.34 (0.18–9.81)	0.77	–	–
Surgeon experience level with MP/VH					
> 100	402	1.00 (ref)		–	
≤ 100	55	1.20 (0.42–3.44)	0.73	–	–
Age at surgery	462	1.00 (0.97–1.03)	0.95	–	–

*Multivariate analysis including *n* = 461 of whom 31 had recurrence in the anterior compartment. CI, confidence interval; RAMuS, rapidly absorbable multifilament suture; SAMoS, slowly absorbable monofilament suture; RAMoS, rapidly absorbable monofilament suture

"a sense of vaginal bulge" [10]. In our study, the main outcome included both an anatomic and symptomatic evaluation of POP, based on data collected from electronic medical records. A great variation in estimates of success after POP surgery is found in the existing literature. The differences in the definition of recurrence might explain the contradictory

Fig. 2 Kaplan-Meier curve showing cumulative incidence of recurrence in the anterior compartment as a function of time from having had an anterior colporrhaphy
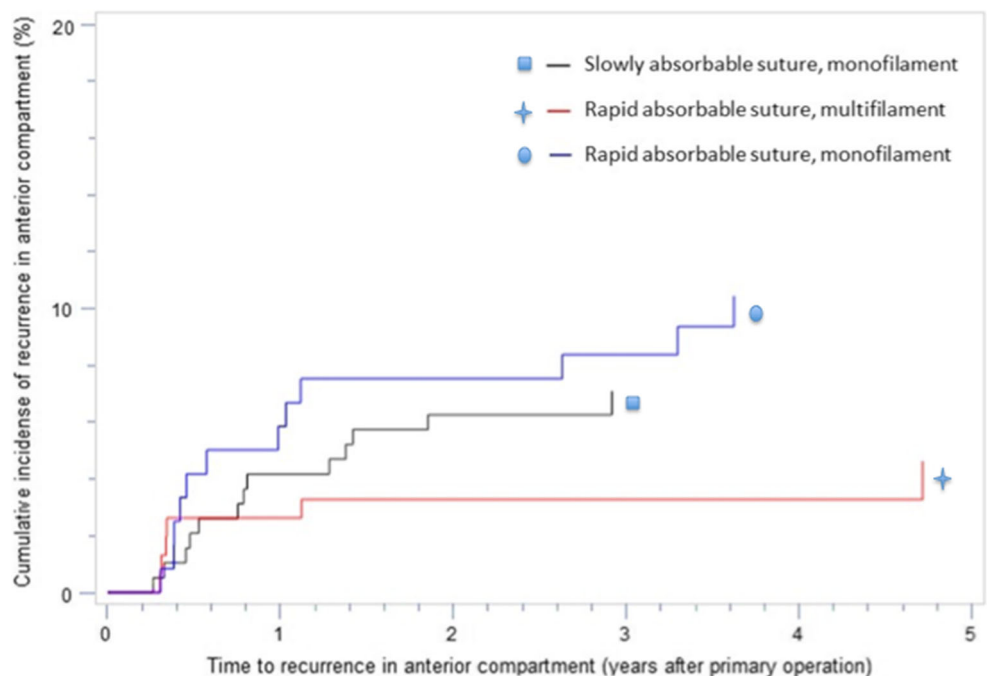
Table 3 Table of sutures

Suture group	Suture name	Time to 50% loss of tensile strenght (days)	Time to complete mass absorption (days)	Monofilament/ multifilament
SAMoS	Monomax®	90–210	390–1080	Mono
	PDS®	28–42	183–238	Mono
RAMoS	Biosyn®	14–21	90–110	Mono
RAMuS	Polysorb®	21	56–70	Multi
	Vicryl®	21	56–70	Multi

Biosyn, Polysorb—Covidien AG, Mansfield, MA; PDS, Vicryl—Ethicon, Inc., Somerville, NJ; Monomax—B. Braun Surgical, S.A. Spain

References: Vicryl, Biosyn and PDS [12]; Polysorb [24, 25]; Monomax: information acquried through personal communication with B. Braun Surgical

findings of this study compared to the Swedish register study. Furthermore, the study only included two groups: rapidly absorbable multifilament and slowly monofilament sutures. There is also a difference in follow-up time where the Swedish study has a follow-up time of 12 months and this study has a follow-up time of 20–48 months.

To our knowledge, only one randomized clinical trial [8, 9] of 66 women has been conducted on the subject of suture material used in anterior colporrhaphy. The women were randomized to mesh or no mesh at the same time as randomized to PDS or Vicryl. Their primary outcome of recurrence was based on data from a questionnaire on POP symptoms and quality of life. No significant difference was found regarding POP symptoms, but the Vicryl group had a significantly better overall quality of life at the 2-year follow-up [8]. Their findings are therefore in line with the present study.

The tendency of the monofilament suture (RAMoS) to have a higher risk of recurrence than the multifilament suture (RAMuS) might be explained by the long absorption time of monofilament sutures. The presence of suture material in wounds as a foreign body induces excessive inflammatory tissue responses, which interfere with the proliferative phase of wound healing and lead to inferior wound strength [12]. The monofilament structure in combination with a rapid loss of tensile strength, when the strength of the healing fascia is still weak, might be an unfavourable composition of suture in anterior colporrhaphy.

Other variables and recurrence

The recurrence rates found in this study after anterior colporrhaphy (4, 7 and 10%, Fig.1) are in accordance with the previous literature [6], though at the lower end of the spectrum. This could be explained by our outcome not including POP-Q stage 2 without symptoms and the large variation in outcome reporting in the existing literature [18]. A previous article concluded that any definition of success after POP surgery should include symptomatic and anatomic criteria and the absence of retreatment, in addition to considering the hymen as a threshold for anatomic success [19]. Moreover, POP-

Q stage 2 prolapse without symptoms is common and not considered an indication for treatment [20]. In our opinion, POP-Q stage 2 without symptoms should therefore not be considered a case of recurrence. Furthermore, only the women who sought medical care after the surgery were examined, and data from private practitioners and clinics were not included in the present study. Both factors could contribute to the low recurrence rates found in the present study.

The preoperative POP-Q stage of prolapse is known to be a risk factor for recurrence after POP surgery [21]. The same tendency was found in the present study, although the finding was not significant.

No significant difference was found between the groups having their first anterior colporrhaphy performed compared to the group having had previous anterior colporrhaphy. However, only 20 women in this study had a previous anterior colporrhaphy done, which might explain the lack of difference. A previous retrospective study found a higher anatomical failure rate after reoperation compared to primary surgery for anterior wall prolapse [22].

The level of surgeon experience had no significant effect on risk of recurrence in the univariate analyses. However, all surgeons in the present study were experienced, working in highly specialized units where these procedures are performed regularly and therefore probably past their learning curve. It could be hypothesised that there would be a difference between inexperienced and experienced surgeons. However, the results of the present study are in line with a previously published register-based study that shows no effect of surgeon experience on recurrence [23].

We measured the suture technique as either one or two layers of suture. Risk of recurrence was similar between the two groups. To our knowledge, there are no other studies on this area.

Strengths and limitations

A strength of the study is the large size of the cohort, including 462 women, and the use of registers with high data completeness, since it is mandatory to report to these databases in

Denmark [15–17]. Furthermore, we have a long follow-up time from 20 to 48 months.

A randomized clinical trial is the gold standard of study design, though difficult to execute with a large cohort. As the present study is register-based, the groups are not completely comparable. Known confounders are accounted for in the statistical analyses, but there might be residual confounding.

Another weakness of the study is the fact that the women had concomitant surgery in addition to anterior colporrhaphy. The type of primary operation (MP or VH) and the number of suture layers are dependent on the surgeon's choice. Clearly, different surgeons prefer different procedures and techniques. This could be due to the different culture in each centre concerning choice of operation, suture material and technique. Furthermore, personal experience might have an impact. The level of surgeon experience was also different between groups, indicating that many experienced surgeons use SAMoS in anterior colporrhaphy. Again, this might be due to the difference in culture and an imaginable unequal rate of experienced surgeons between centres.

Since this is a secondary study to the primary study conducted by Tolstrup et al. [14], no power calculation was made. However, a power analysis was performed after the study and showed that a group size of 140 women in each group was sufficient to detect a significant difference of 5% versus 15% recurrence, with an alpha of 0.05 and beta of 0.8. Thus, our sample size is large enough to detect a difference of this size; however, the study might be underpowered to find a smaller difference.

Nevertheless, as the RAMuS had the lowest observed recurrence rate in this study, we did not find evidence to support our hypothesis that the use of RAMuS would predispose patients to recurrence.

Conclusion

In this study, the use of rapidly absorbable multifilament suture compared to slowly absorbable monofilament suture does not seem to lead to a higher risk of recurrence after anterior colporrhaphy

Compliance with ethical standards

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