



Nationwide Propensity-Score Matched Study of Mesh Versus Suture Repair of Primary Ventral Hernias in Women with a Subsequent Pregnancy

Erling Oma^{1,3} · Thue Bisgaard^{2,3} · Lars N. Jorgensen^{1,3} · Kristian K. Jensen¹

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Abstract

Background Mesh reinforcement is recommended for repair of primary ventral hernias; however, this recommendation does not consider a potential subsequent pregnancy. The aim of this prospective cohort study was to compare mesh and suture repair of a primary ventral hernia in women with a subsequent pregnancy.

Methods All women of childbearing age who underwent repair of a primary ventral hernia between 2007 and 2014 were identified in the Danish Ventral Hernia Database. Data were merged with the Danish Medical Birth Registry. Women with a subsequent pregnancy and a propensity-score matched control group of women without a subsequent pregnancy were included. A structured questionnaire was sent out, and the primary outcome was hernia recurrence, while the secondary outcome was chronic postoperative pain.

Results In total, 632 women were included, of whom 441 (69.8%) responded to the questionnaire (195 and 246 with and without subsequent pregnancy, respectively). The 8-year cumulative incidence of recurrence was 24.8%. In women with a subsequent pregnancy, mesh repair was associated with a decreased risk of recurrence (hazard ratio 0.44, 95% CI 0.20–0.95, $p = 0.038$, number needed to treat = 5.1) and an increased risk of chronic pain (OR 5.07, 95% CI 1.20–23.38, $p = 0.029$, number needed to harm = 4.7) compared with suture repair, in multivariable analyses.

Conclusions Mesh repair was associated with a decreased risk of recurrence, but an increased risk of chronic pain, compared with suture repair in women with a subsequent pregnancy.

Introduction

Repair of a primary ventral hernia is a commonly performed surgical procedure on women of childbearing age [1]. There is strong evidence for mesh reinforcement for umbilical hernia repair to decrease the risk of recurrence with no increased risk of chronic pain [2, 3]. However, this recommendation is based on studies that did not consider the additional strain of the abdominal wall during a possible subsequent pregnancy. Watchful waiting is safe during pregnancy and pre-pregnancy ventral hernia repair is associated with hernia recurrence [4–7]. Thus, conservative management seems recommendable for women with no or little discomfort who plan a future pregnancy. Nonetheless,

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✉ Erling Oma
erlingom@gmail.com

¹ Digestive Disease Center, Bispebjerg Hospital, Bispebjerg Bakke 23, 2400 Copenhagen, NV, Denmark

² Gastrounit, Surgical Division, Centre for Surgical Research (CSR), Hvidovre Hospital, Hvidovre, Denmark

³ University of Copenhagen, Copenhagen, Denmark

when a pre-pregnancy repair is indicated, it is unclear if mesh is superior to suture repair as regards to subsequent development of recurrence or chronic pain [8].

The aim of the present study was to examine mesh versus suture repair of a primary ventral hernia in women of childbearing age who subsequently became pregnant. The primary outcome was hernia recurrence, and the secondary outcome was chronic postoperative pain.

Materials and methods

This was a prospective nationwide cohort study reported according to the STROBE statement [9]. The study population consisted of women aged 15–45 years who underwent repair of a primary ventral hernia (non-recurrent umbilical or epigastric hernia), hereafter referred to as index repair. The Danish Ventral Hernia Database was queried for eligible women between January 1, 2007, and December 31, 2013. Data were merged with the Danish Medical Birth Registry using the unique Danish personal registration number. Women were grouped according to whether or not they had given childbirth after the index repair during the inclusion period. Papers including other registry-based outcomes on this cohort or a subgroup hereof have previously been published [5, 8].

The present study cohort included all women who had been pregnant following the index repair and a 1:2 propensity-score matched control group of women who had not been pregnant subsequently. Vital status and postal address on the cohort was retrieved from the Danish Civil Registry. Women who died or emigrated during the study period were excluded. The women were invited to participate in the study by answering a previously validated questionnaire to identify patients with ventral hernia recurrence [10]. Women without subsequent pregnancy during the inclusion period were asked about pregnancy to identify childbirths from January 1, 2014, and onwards. Women who reported both recurrence and subsequent pregnancy were asked whether the hernia recurred before or after becoming pregnant to adequately evaluate predictive associations. A pregnancy loss prior to 22-week gestation is not registered in the Danish Medical Birth Registry. Considering identification of a subsequent pregnancy in the questionnaire, the respondents were asked to disregard any pregnancy loss prior to 5-month gestation. Thus, a subsequent pregnancy was defined as a pregnancy of minimum 22-week gestation in this study. Any additional pregnancies following the first childbirth after the index repair were not considered in the present study. The questionnaire also included questions on current pain in the operated region (none, mild, moderate or severe pain during the last week), smoking status at the time of index

repair and current height and weight. The questionnaire was sent by mail up to three times followed by up to three phone contact attempts, conducted between January and June 2018. All women were above 18 years of age at the time of follow-up. Self-reported doubt of recurrence was resolved by a phone interview according to a modified PINQ-PHONE protocol, consisting of three questions and a do-it-yourself Valsalva maneuver [11]. The primary and secondary outcomes were analyzed separately for the group of women exposed to a subsequent pregnancy and the control group of women without a subsequent pregnancy. Recurrence was defined as self-reported clinical recurrence or reoperation for recurrence. Chronic postoperative pain was defined as self-reported pain of moderate or severe intensity [12].

Statistics

Matching was based on a propensity score using logistic regression analysis with the nearest neighbor method without replacement and a caliper width of 0.2 [13, 14]. The model included age, hernia defect size, hernia type (umbilical vs. epigastric), repair type (mesh vs. suture) and surgical approach (open vs. laparoscopic). Comparison of baseline characteristics was performed with student's *t* test and Mann–Whitney U for Gaussian and non-Gaussian variables, respectively. Categorical variables were analyzed with χ^2 test or Fisher's exact test, as appropriate. The risk of hernia recurrence was analyzed with uni- and multivariable Cox proportional hazards regression analyses reported as hazard ratios (HR) and 95% confidence intervals (CI). Follow-up time was from index repair until date of reoperation for recurrence or filling in the questionnaire. Thus, only one (first) recurrence was considered for each participating woman, as follow-up was ended at the time of reoperation for recurrence. The variable chronic pain was dichotomized (none/mild [no chronic pain] vs. moderate/severe [chronic pain]) and analyzed with uni- and multivariable logistic regression analyses, and reported as odds ratios (OR) and 95% CI. The above models included mesh versus suture (exposure of interest) and pre-selected baseline characteristics to adjust for known and potential effect modifiers and confounders, in compliance with the number of events [15, 16]. The performance of the multivariable models was assessed with Hosmer–Lemeshow goodness of fit test. Discriminative ability of the logistic regression model was further tested with concordance statistics. Proportional hazards assumptions in the Cox models were checked according to scaled Schoenfeld residuals. Hernia defect size was calculated as $\pi \times (\text{maximum vertical diameter}/2) \times (\text{maximum horizontal diameter}/2)$ [17]. Surgical approach was left out of the analyses, as all laparoscopic procedures were performed with mesh.

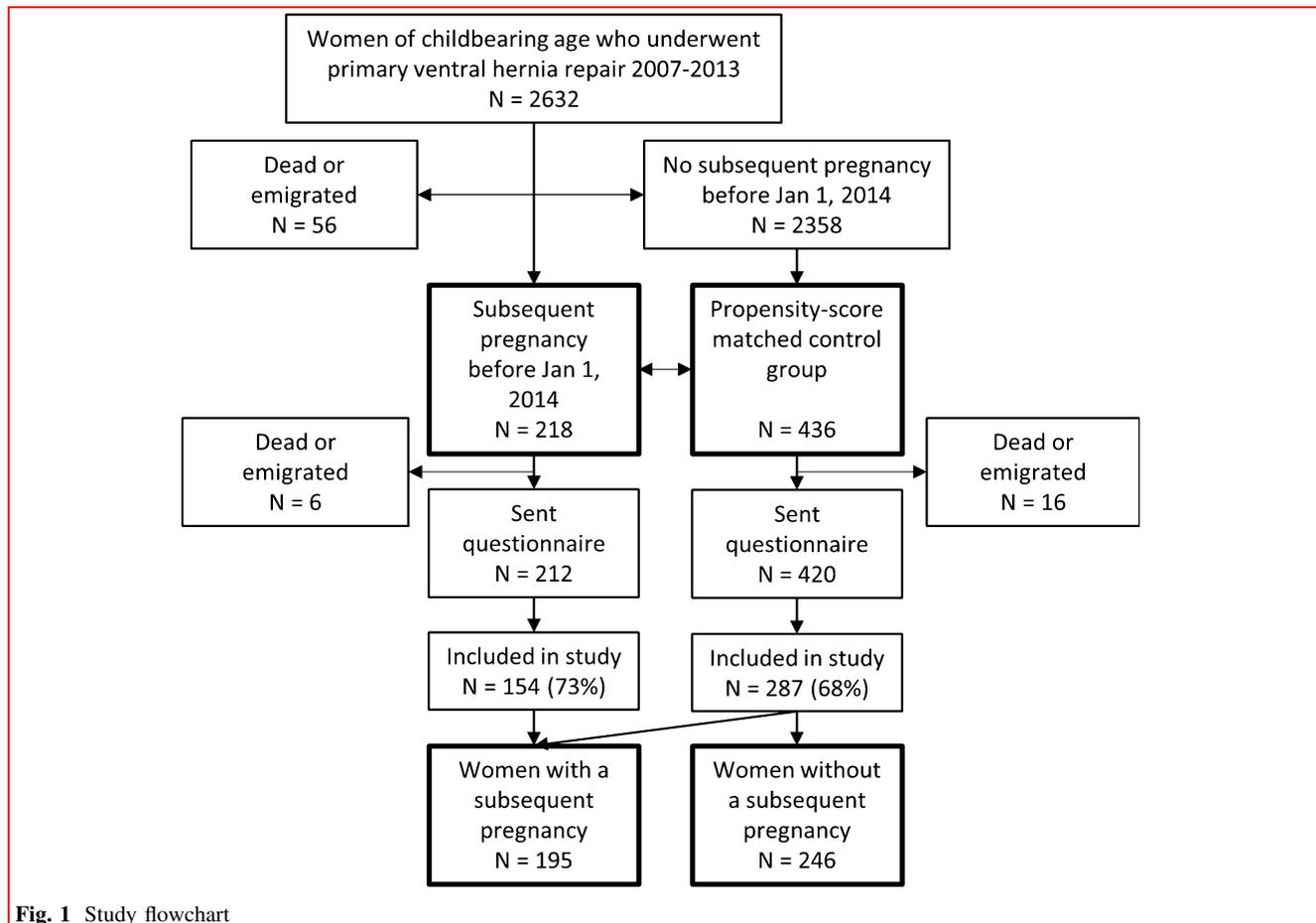


Fig. 1 Study flowchart

Numbers needed to treat/harm (NNT/NNH) were calculated based on event rates in the suture repair group and the adjusted hazard or odds ratios comparing mesh with suture repair [18, 19]. In the analyses, a woman was considered exposed to a subsequent pregnancy from 267 days preceding the date of childbirth [20]. The analyses were performed in subgroups of women with and without subsequent pregnancy, respectively. Additional subgroup analyses were performed for women with small-sized hernias, defined as a horizontal fascial defect of 2 cm or less [21]. A *p* value below 0.05 was considered significant. Women with missing data were left out of the analyses of the missing variable only. All analyses were performed with R v.3.1.2 (Vienna, Austria, R-project.org). The study was approved by the Danish Data Protection Agency (Ref. BFH-2017-025) and the regional Ethics Committee (Ref. H-17002135).

Results

In total, 2 632 women between 15 and 45 years of age underwent repair of a primary ventral hernia during the 7-year inclusion period (Fig. 1). In total, 218 women had been pregnant following the index repair. These women were propensity-score matched with 436 women without a subsequent pregnancy. Of these, 22 women had subsequently died or emigrated. Thus, a questionnaire was sent out to 632 women, of whom 441 responded (69.8%). Responders were mean 1.2 years older than non-responders and had more often undergone umbilical than epigastric hernia repair (69.8 and 60.2% of responders and non-responders underwent umbilical hernia repair, respectively). There were no other significant differences between responders and non-responders. Forty-one (14.3%) of the women with no subsequent pregnancy during the inclusion period reported a childbirth during the follow-up after January 1, 2014, and were relocated to the pregnancy-exposed group (Table 1). There were no significant differences in baseline characteristics between women with and without a subsequent pregnancy ($n = 195$ vs. $n = 246$),

Table 1 Descriptive characteristics of included women of childbearing age who underwent repair of a primary ventral hernia with and without subsequent pregnancy

Variable	Subsequent pregnancy, <i>N</i> = 195		No subsequent pregnancy <i>N</i> = 246	
	Mesh repair <i>n</i> = 45	Suture repair <i>n</i> = 150	Mesh repair <i>n</i> = 58	Suture repair <i>n</i> = 188
Hernia defect (cm ²)	2.9 (0.8–4.7)	0.8 (0.5–0.8)*	2.9 (0.8–4.9)	0.8 (0.4–0.8)†
Hernia type				
Epigastric	13 (28.9)	44 (29.3)	23 (39.7)	53 (28.2)
Umbilical	32 (71.1)	106 (70.7)	35 (60.3)	135 (71.8)
Age, mean (sd) (year)	30.2 (4.9)	30.2 (4.9)	33.3 (4.7)	31.4 (5.7)†
Approach				
Laparoscopic	9 (20.0)	0 (0.0)*	11 (19.0)	0 (0.0)†
Open	36 (80.0)	150 (100.0)	47 (81.0)	188 (100.0)
Emergency repair	4 (8.9)	12 (8.0)	2 (3.4)	18 (9.6)
Nulliparous at index repair	8 (17.8)	35 (23.3)	3 (5.2)	35 (18.6)†
Body mass index (kg/m ²)	23.8 (21.8–28.9)	23.0 (20.9–26.0)	25.0 (21.9–30.1)	23.1 (21.2–27.1)†
Missing	2	0	0	1
Smoker at index repair	8 (17.8)	36 (24.0)	15 (25.9)	44 (23.4)
Time to pregnancy, y	1.9 (0.8–3.1)	1.4 (0.7–2.7)	–	–
Follow-up, y	8.0 (6.8–9.6)	8.4 (6.9–9.4)	7.5 (6.0–9.0)	7.2 (6.0–8.6)

The given values are *n* (%) or median (interquartile range) unless otherwise stated

*Significant difference between groups (mesh vs. suture) for women with subsequent pregnancy

†Significant difference between groups (mesh vs. suture) for women without subsequent pregnancy

besides age (mean 30.2 ± 4.9 vs. 31.8 ± 5.5 years, $p < 0.001$). The median time from index repair to the first day of a subsequent pregnancy was 1.5 years (interquartile range 0.7–2.8 years) with no difference comparing patients undergoing mesh versus suture repair. The overall median follow-up was 7.2 years (interquartile range 5.8–8.9 years). The horizontal fascial defect was less than 2 cm in 405 women (91.8%) and less than 1 cm in 340 women (77.1%).

Hernia recurrence

In total, 127 (28.8%) women reported hernia recurrence (clinical recurrence, $n = 65$ [14.7%]; reoperation for recurrence, $n = 62$ [14.1%]). The overall 8-year cumulative incidence of recurrence was 24.8% (95% CI 20.3–29.2%). The crude cumulative incidence of recurrence for mesh versus suture repair for women with and without subsequent pregnancy, respectively, is presented in Fig. 2.

In the group of women with a subsequent pregnancy, mesh repair was associated with a decreased risk of recurrence compared with suture repair (HR 0.44, 95% CI 0.20–0.95, $p = 0.038$, NNT = 5.1) in a multivariable analysis. Furthermore, women who were parous at the time of index repair had an increased risk of recurrence compared with nulliparous women (Table 2). Mesh was

consistently associated with a decreased risk of recurrence compared with suture repair (HR 0.38, 0.15–0.96, $p = 0.041$) in a multivariable subgroup analysis of women with a subsequent pregnancy and a small-sized hernia (mesh repair, $n = 34$; suture repair, $n = 145$).

In the control group of women without a subsequent pregnancy, type of repair was not associated with recurrence (mesh repair HR 0.92, 0.49–1.73, $p = 0.805$). The same nonsignificant results (mesh repair HR 1.19, 0.57–2.50, $p = 0.647$) were found in a multivariable model restricted to women with a small-sized hernia (mesh repair, $n = 41$; suture repair, $n = 185$).

Chronic postoperative pain

Fifty women (11.3%) reported chronic postoperative pain (moderate intensity, $n = 33$ [7.5%]; severe, $n = 17$ [3.9%]), of which 18 (17.5%) and 32 (9.5%) had a mesh and suture repair, respectively. In the group of women with a subsequent pregnancy, mesh repair was independently associated with an increased risk of chronic pain (OR 5.07, 1.20–23.38, $p = 0.029$, NNH = 4.7) compared with suture repair. Further, hernia recurrence was also independently associated with chronic pain (Table 3). In the control group of women without a subsequent pregnancy, type of repair was not associated with chronic pain (mesh repair OR 1.95,

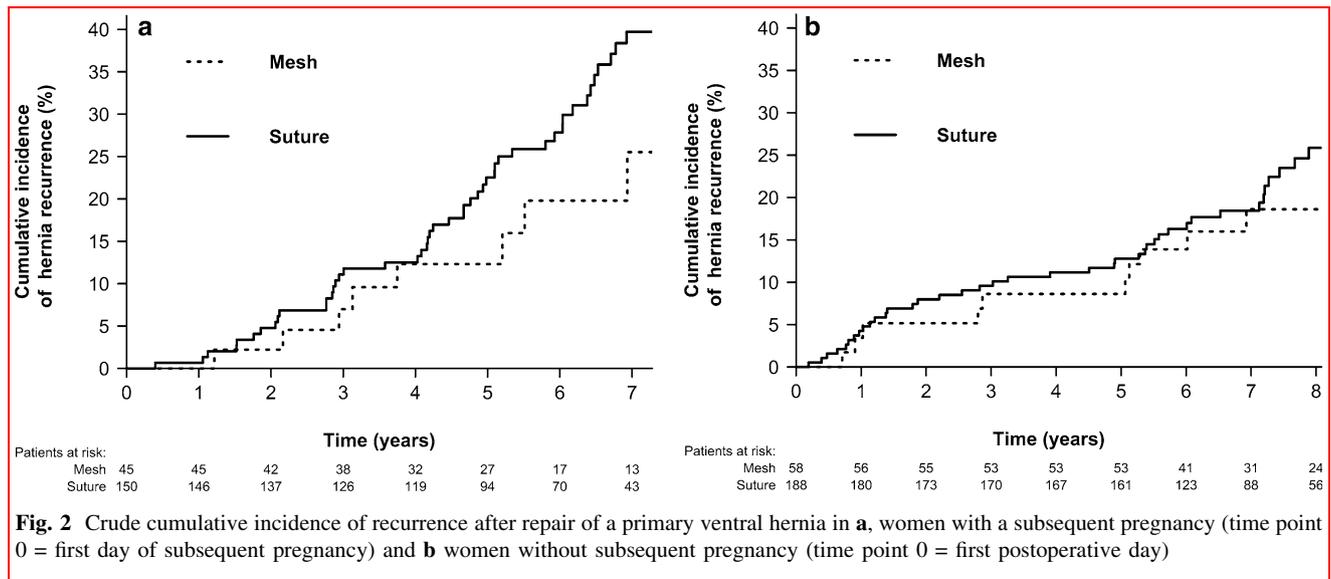


Table 2 Cox proportional hazards regression analyses for hernia recurrence ($n = 127$) after repair of a primary ventral hernia

Variable	Women with a subsequent pregnancy						Women without a subsequent pregnancy					
	Univariable			Multivariable			Univariable			Multivariable		
	HR	95% CI	<i>p</i>	HR	95% CI	<i>p</i>	HR	95% CI	<i>p</i>	HR	95% CI	<i>p</i>
Mesh repair	0.60	0.30–1.18	0.139	0.44	0.20–0.95	0.038	0.92	0.52–1.62	0.760	0.92	0.49–1.73	0.805
Hernia defect, per unit (cm ²) increase	1.03	0.90–1.04	0.392	0.97	0.90–1.04	0.350	0.99	0.93–1.05	0.792	1.00	0.94–1.07	0.995
BMI, per unit (kg/m ²) increase	0.97	0.92–1.03	0.364	0.98	0.92–1.04	0.463	1.02	0.98–1.08	0.346	1.03	0.98–1.08	0.263
Age, per unit (year) increase	1.03	0.97–1.08	0.345	1.00	0.94–1.06	0.992	0.94	0.90–0.98	0.004	0.94	0.89–0.99	0.024
Smoker	0.92	0.51–1.68	0.796	0.79	0.41–1.51	0.479	1.06	0.61–1.84	0.844	0.95	0.53–1.69	0.859
Umbilical hernia	1.07	0.62–1.83	0.818	1.04	0.59–1.81	0.900	0.74	0.45–1.23	0.243	0.79	0.47–1.31	0.355
Emergency repair	0.66	0.24–1.82	0.420	0.65	0.24–1.81	0.413	0.50	0.16–1.59	0.238	0.36	0.11–1.19	0.094
Parous at time of index repair	2.24	1.06–4.76	0.035	2.89	1.20–6.96	0.018	0.54	0.30–0.98	0.044	0.67	0.32–1.40	0.287

HR hazard ratio, CI confidence interval, BMI body mass index

Hosmer–Lemeshow goodness of fit revealed $p = .690$ and $p = .636$ in the multivariable model for women with and without a subsequent pregnancy, respectively, hence indicating no evidence of poor fit

0.83–4.54, $p = 0.119$). Multivariable subgroup analyses of women with a small-sized hernia revealed consistent results in the group of women with a subsequent pregnancy (mesh repair OR 5.46, 1.09–28.58, $p = 0.037$) and in the control group without a subsequent pregnancy (mesh repair OR 1.35, 0.44–3.72, $p = 0.578$). Test for effect modification showed no interaction between recurrence and mesh in either group.

Discussion

It is recommended that repair of a primary ventral hernia is performed with mesh; however, the optimal surgical technique for women who plan a future pregnancy is not clear [2, 3]. In this study, it was found that mesh was associated with a decreased risk of recurrence, but an increased risk of chronic pain compared with suture repair of a primary ventral hernia in women with a subsequent pregnancy.

Previous studies have found that pregnancy following ventral hernia repair is associated with recurrence and a watchful waiting policy for primary ventral hernias is safe during pregnancy [4, 5, 7]. Hence, watchful waiting during

Table 3 Logistic regression analyses for chronic pain ($n = 50$) after repair of a primary ventral hernia

Variable	Women with a subsequent pregnancy						Women without a subsequent pregnancy					
	Univariable			Multivariable			Univariable			Multivariable		
	OR	95% CI	<i>p</i>	OR	95% CI	<i>p</i>	OR	95% CI	<i>p</i>	OR	95% CI	<i>p</i>
Mesh repair	1.94	0.64–5.45	0.217	5.07	1.20–23.38	0.029	2.07	0.93–4.48	0.067	1.95	0.83–4.54	0.119
Hernia recurrence	8.32	2.79–30.65	<0.001	14.45	4.18–65.92	<0.001	2.06	0.94–4.41	0.064	1.98	0.89–4.29	0.085
Hernia defect, per unit (cm ²) increase	0.99	0.82–1.06	0.835	0.91	0.66–1.07	0.458	1.00	0.91–1.05	0.892	0.99	0.83–1.04	0.779
BMI, per unit (kg/m ²) increase	1.03	0.93–1.13	0.512	1.07	0.95–1.18	0.225	1.08	1.01–1.16	0.023	1.07	0.99–1.15	0.051

Hosmer–Lemeshow goodness of fit revealed $p = .315$ and $p = .685$ in the multivariable model for women with and without a subsequent pregnancy, respectively, hence indicating no evidence of poor fit. Corresponding C-statistics were 0.82 and 0.67, thus indicating high and mediocre discriminative ability in the group of women with and without a subsequent pregnancy, respectively

OR odds ratio, CI confidence interval, BMI body mass index

the full childbearing period seems recommendable for asymptomatic or mildly symptomatic primary ventral hernias. However, when surgical repair is required, for instance due to severe pain, and the patient plans a future pregnancy, it has been sparsely examined whether or not to place a mesh [1, 22]. In total, 27 women with a suture or mesh repair of a primary ventral hernia and a subsequent pregnancy have been examined in a few case-series, with no reported recurrences [22]. In 2016, a registry-based study reported no difference in recurrence rates comparing pre-pregnancy mesh and suture repair for 224 women [8]. This could be explained by a type II error due to an underestimation of recurrence rates, which were based on reoperation or clinical recurrence from administrative hospital registrations. In the present study, mesh was associated with a decreased risk of recurrence compared with suture repair for women with a subsequent pregnancy. Thus, compared with a suture repair, mesh repair seems more capable of protecting the previous hernia site from recurrence during the extensive abdominal wall strain in pregnancy. Further, women who had given birth previously were at increased risk of recurrence compared with nulliparous women at the time of index repair. This could be due to an increased prevalence of abdominal rectus diastasis in parous women, which is associated with hernia recurrence [23, 24]. Further exploration of this hypothesis was inaccessible, as concomitant diastasis is not reported in the Danish Ventral Hernia Database.

There was no difference in the risk of recurrence after mesh versus suture repair in the control group of women without a subsequent pregnancy. About three-quarters of the women included in the present study had hernias with a horizontal fascial defect of 1 cm or less, and more than 90% were 2 cm or less. Kaufmann et al. recommend mesh for defect sizes down to 1 cm, but the randomized trial did

not find a significant difference in the subgroup of patients with a defect between 1 and 2 cm [3]. A previous Danish cohort study found that mesh was associated with a decreased risk of recurrence compared with suture repair for defects up to 2 cm, but did not report a confounder-adjusted estimate for the subgroup of patients with a defect of 1 cm or less [2]. The absolute risk reduction comparing mesh and suture repair seems smaller for patients who do not become pregnant subsequently, and the lack of a statistically significant difference might be due to insufficient power. However, in low-risk patients, there might be a defect size threshold below which suture repair equals mesh repair regarding recurrence rates.

A high rate of chronic postoperative pain was reported in the present study. In the United Kingdom, complications following mesh hernia repair, notably chronic pain, have recently caught the public eye [25]. Other studies on primary ventral hernia have reported chronic pain rates from 5 to 8% [2, 3, 26]. Recurrence is an associated risk factor for chronic pain, and this could partially explain the higher pain rate in the current study compared with previous studies [27]. In women with a subsequent pregnancy, mesh was associated with an increased risk of chronic pain compared with suture repair adjusted for potential confounders. There are case reports of severe postoperative pain during pregnancy after mesh repairs [28, 29]. The less elastic mesh compared with the stretched abdominal wall during pregnancy could theoretically explain this finding, and perhaps also induce sustained chronic pain after childbirth [30]. Based on the current literature, a suture repair might be the better choice in those symptomatic women who require a repair prior to planned pregnancy, thus postponing a possible mesh repair until after the last pregnancy in case of hernia recurrence. However, larger prospective studies comparing pre-pregnancy repair and

watchful waiting with the primary aim of examining hernia-related quality of life seems warranted, before more extensive treatment recommendations can be formulated. Similar to previous studies on the general adult population, no difference was noted in the risk of chronic pain comparing mesh and suture in the control group of women without a subsequent pregnancy [2, 3, 26]. Further, younger age was likewise associated with an increased risk of recurrence in this group [2].

This study has its limitations. Even though the groups were propensity-score matched and estimates were adjusted for known and potential confounders, there was a risk of selection bias due to the non-randomized study design. Further, despite no clinically relevant differences between responders and non-responders, there is a risk of participation bias, as about 30% did not respond. The sample size in the present study did not allow for subgroup analyses of the influence from suture type, mesh type, placement or fixation on development of chronic pain. Adjustment for preoperative pain was also not possible in this study, which might be predictive for postoperative chronic pain, as reported for groin hernia repair [31]. Strengths of the study include the long-term prospective follow-up on nationwide “real world” data associated with high external validity. In general, the multivariable predictive models performed well, ideally; however, these models should be validated in a separate patient cohort.

In conclusion, compared with suture repair, the benefits attributable to mesh reinforcement were offset in part by mesh-associated chronic pain in women who became pregnant following repair of a primary ventral hernia.

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Compliance with ethical standards

Conflict of interest All authors declare that they have no conflicts of interest.

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