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Preventing Parastomal Hernia After Ileal Conduit by the Use of a Prophylactic Mesh: A Randomised Study

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Abstract

Background: Parastomal hernia (PSH) after urinary diversion with ileal conduit is frequently a clinical problem.
Objective: To investigate whether a prophylactic lightweight mesh in the sublay position can reduce the cumulative incidence of PSH after open cystectomy with ileal conduit.
Design, setting, and participants: From 2012 to 2017, we randomised 242 patients 1:1 to conventional stoma construction ($n = 124$) or prophylactic mesh ($n = 118$) at three Swedish hospitals (ISRCTN 95093825).
Outcome measurements and statistical analysis: The primary endpoint was clinical PSH, and secondary endpoints were radiological PSH assessed in prone position with the stoma in the centre of a ring, parastomal bulging, and complications from the mesh.
Results and limitations: Within 24 mo, 20/89 (23%) patients in the control arm and 10/92 (11%) in the intervention arm had developed a clinical PSH ($p = 0.06$) after a median follow-up of 3 yr, corresponding to a hazard ratio of 0.45 (confidence interval 0.24–0.86, $p = 0.02$) in the intervention arm. The proportions of radiological PSHs within 24 mo were 22/89 (25%) and 17/92 (19%) in the two study arms. During follow-up, five patients in the control arm and two in the intervention arm were operated for PSH. The median operating time was 50 min longer in patients receiving a mesh. No differences were noted in proportions of Clavien-Dindo complications at 90 d postoperatively or in complications related to the mesh during follow-up.
Conclusions: Prophylactic implantation of a lightweight mesh in the sublay position decreases the risk of PSH when constructing an ileal conduit without increasing the risk of complications related to the mesh. The median surgical time is prolonged by mesh implantation.
Patient summary: In this randomised report, we looked at the risk of parastomal hernia after cystectomy and urinary diversion with ileal conduit with or without the use of a prophylactic mesh. We conclude that such a prophylactic measure decreased the occurrence of parastomal hernias, with only a slight increase in operating time and no added risk of complications related to the mesh.

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1. Introduction

The literature offers very little information on the occurrence of parastomal hernias (PSHs), and the proportion of patients being subjected to surgical repair after radical cystectomy and ileal conduit [1]. Studies in this context are often hampered by simultaneous reporting of several types of long-term complications after cystectomy, by the use of single-centre design, and by not applying time-to-event statistics [2,3]. Furthermore, these retrospective investigations include only limited numbers of patients. In the largest available review [4], which considered a total of 3170 patients treated with radical cystectomy and ileal conduit, the proportions reported to have a clinical PSH diagnosis ranged from 4% to 28%, and even larger proportions were noted for patients with a radiological diagnosis of PSH.

In that review, surgical repair was offered to 8–75% of the patients with PSHs, and recurrence following repair ranged from 27% to 50% [4].

There are currently conflicting results from randomised studies investigating the use of a prophylactic mesh on the effect on PSH when creating a colostomy [5,6]. It seems that the application of such a prophylactic lightweight mesh in the sublay position when performing an ileal conduit after radical cystectomy does not generate mesh-related complications [7,8]. Considering that a PSH constitutes a significant clinical problem for the individual patient, we performed a prospective randomised multicentre study to ascertain whether the use of a prophylactic mesh can decre the risk of developing clinical PSH.

2. Patients and methods

2.1. Patients and recruitment

Out of 432 patients subjected to radical cystectomy and ileal conduit, 242 accepted study inclusion at two university hospitals (Skåne University Hospital in Malmö [$n = 97$] and Örebro University Hospital in Örebro [$n = 69$]) and one county hospital (Helsingborg County Hospital in Helsingborg [$n = 76$]) in Sweden between August 2012 and May 2017. Randomisation was performed using closed envelopes without blinding. Inclusion criteria were cystectomy and ileal conduit in a patient >18 yr of age in combination with the absence of a previous stoma. Exclusion criteria were previous stoma and a lack of informed consent.

2.2. Surgical details of mesh insertion

Preoperatively, the stoma location was marked on the skin by a stoma nurse within the area of the right rectus abdominis muscle, except in Örebro University Hospital where it was performed by the operating urologist. A Vypro mesh (10 cm × 10 cm; Ethicon) was used. Further details are given in the Supplementary material (surgical methods).

2.3. Follow-up, surveillance, outcomes, and mode of measurement

The primary endpoint clinical PSH and the secondary endpoints radiological PSH, parastomal bulging, and complications from the mesh were assessed at follow-up visits at 6, 12, and 24 mo postoperatively, as well as at later visits scheduled at the discretion of the treating urologist. The occurrence of a clinical PSH and bulging around the stoma were registered without any a priori definitions applied for clinical PSH or parastomal bulging, and both symptomatic and asymptomatic findings were reported. At the same time intervals, patients underwent computed tomography (CT) for oncological follow-up. This was done with the patient in the prone position, with the stoma placed in the centre of an inflatable plastic ring, which is reported to correlate with clinical PSH (kappa value 0.80) [9]. The CT scan was performed during simultaneous straining, adding assessment of radiological hernia to oncological outcomes at the evaluation of the CT by the radiologist. At the end of follow-up, all patients had at least one follow-up visit to assess clinical PSH, but the exact number of clinical visits was not registered. The physicians and radiologists assessing for PSH were not blinded to the randomisation arm. During follow-up, some patients were referred to additional CT examinations, and also after 24 mo additional CT investigations were performed to rule out bladder cancer metastases at the discretion of the treating urologist. The exact number of CT investigations per patient was not registered as these not were performed in prone position. However, the information was used if a PSH was reported in any of these investigations, even if not performed in prone position. Of all patients, 203 had undergone at least one CT scan in prone position during follow-up as described above, equally distributed between the control group and the intervention group (83% and 85%, respectively). The CT scans showing a PSH were reviewed (F.L. and T.J.) and classified according to the study of Moreno-Matias et al [10] as follows: I = a hernia sac containing stoma loop; II = a hernia sac containing the omentum; and III = a hernia sac containing an intestinal loop other than the stoma loop. A retrospective review of patient charts was conducted to obtain information on postoperative complications at 90 d after surgery and on long-term complications related to PSH and mesh implantation.

The study was registered on a trial site (ISRCTN 95093825) and approved by the Research Ethics Board of Lund University (2012/336).

2.4. Statistics

We anticipated 20% clinical PSHs in the control arm [4] and 5% in the intervention arm at 2 yr, based on reported proportions of PSHs after using prophylactic mesh in general surgery from two small randomised trials [11,12]. Considering that approximately 50% of randomised bladder cancer patients will succumb to the disease within 2 yr of surgery, we doubled the required sample size and planned to enrol 240 patients in the present study to achieve a power of 0.8 to detect a reduction in PSH rate from 20% to 5% ($\alpha = 0.05$) at 2-yr follow-up. In analysis of the data, continuous variables were tabulated using median and interquartile ranges (IQRs). When appropriate, statistical comparisons were performed with a standard t test. Categorical variables were tabulated and, when applicable, were compared using a chi-square test. This was done except when small classes made it inappropriate, and in such cases, Fisher's exact test was used and noted accordingly. The primary endpoint PSH was assessed by survival analysis methods, with follow-up time representing the time to PSH if observed, as were secondary endpoints radiological PSH and parastomal bulging. In other circumstances, patients were censored at the date of last clinical follow-up or the date of death. At the end of follow-up, 157 patients were alive. The primary analysis was a time-to-event analysis comparing the patients who were and those who were not treated with a mesh instead of the binary endpoint (PSH within 24 mo) used when performing the power calculation described above. The reason for this was emerging knowledge published after the start of the study, reporting occurrence of PSH also after 2 yr and progression to more severe hernias in more than one out of three patients during further follow-up [13]. The risks of clinical and radiological PSH and parastomal bulging were analysed by

multivariable Cox proportional hazard models adjusting for the following covariates: mesh or no mesh, operating hospital, body mass index (BMI; per increased unit), and use of preoperative chemotherapy. All analyses were performed using the R package, version 3.6.1 [14]. The CONSORT checklist for reporting randomised trials are available in the Supplementary material.

3. Results

A total of 242 patients scheduled to undergo open radical cystectomy for bladder cancer and ileal conduit were randomised 1:1 to prophylactic mesh implantation or conventional stoma formation (Fig. 1). One patient randomised to the control group had severe adhesions after previous abdominal surgery, and it was not technically feasible to construct an ileal conduit; this patient instead received a ureteroureteric anastomosis and unilateral nephrostomy. The patient and treatment characteristics of the 241 evaluable individuals were well balanced between the study groups (Table 1), and the median follow-up time after cystectomy was 3 (IQR 2–4) yr in the control group and 3 (IQR 2–5) yr in the mesh group, for patients without PSH. Within 6, 12, and 24 mo, 5/117 (4%), 9/103 (9%), and 20/89 (23%) patients in the control arm and 1/111 (1%), 7/100 (7%), and 10/92 (11%) patients in the intervention arm, respectively, had developed a clinical PSH (Table 2). The corresponding proportions of radiological PSHs within 24 mo were 22/89 (25%) and 17/92 (19%; not significant), and the raw numbers at the end of follow-up are reported in Table 3. Parastomal bulging with no hernia was a clinical finding within 24 mo in 13/89 (15%) patients without a prophylactic mesh and 22/92 (24%) with a mesh (not significant). The cumulative incidence of clinical PSH in the two treatment arms is illustrated in Fig. 2, corresponding to a hazard ratio (HR) of 0.45 (confidence interval [CI] 0.24–0.86, $p = 0.02$).

When investigating the risk of clinical PSH in a multivariable Cox proportional hazard model adjusting for mesh or no mesh according to randomisation, operating hospital, BMI (per increased unit), and use of preoperative chemotherapy, prophylactic mesh (HR 0.49 [CI 0.26–0.95, $p = 0.04$]), BMI (HR 1.08 per unit [CI 1.01–1.16, $p = 0.02$]), and surgery in one of the hospitals (HR 3.34 [CI 1.39–8.06, $p = 0.007$]) were associated with such a risk (Supplementary Table 1). Corresponding associations with the secondary endpoints radiological PSH and parastomal bulging are given in Supplementary Tables 2 and 3, respectively. The median operating time was 50 min longer for patients who received a prophylactic mesh than for those who did not (415 vs 365 min; $p = 0.007$). However, no increases in the rates of postoperative Clavien-Dindo grade 1–2 and 3–5 complications at 90 d were observed in patients with a mesh compared with those without (Table 1). One patient in the intervention arm (ie, with a prophylactic mesh) developed postoperative partial ischaemia in the ileal conduit, and one patient in the control arm (ie, without a mesh) developed complete ischaemia in the ileal conduit and had to undergo a reoperation within 90 d of the primary surgery. No other potential mesh-related complications were observed within 90 d of surgery (Table 4). During follow-up, five patients in the control arm and two in the intervention arm were operated for PSH. Another patient in the control arm had a reoperation for an elongated stoma, and one additional patient in the intervention arm had a reoperation on the ileal conduit for a flat stoma bud and this was performed locally without the need for laparotomy. One patient in the intervention arm had a minor stomal prolapse at follow-up, which was treated conservatively.

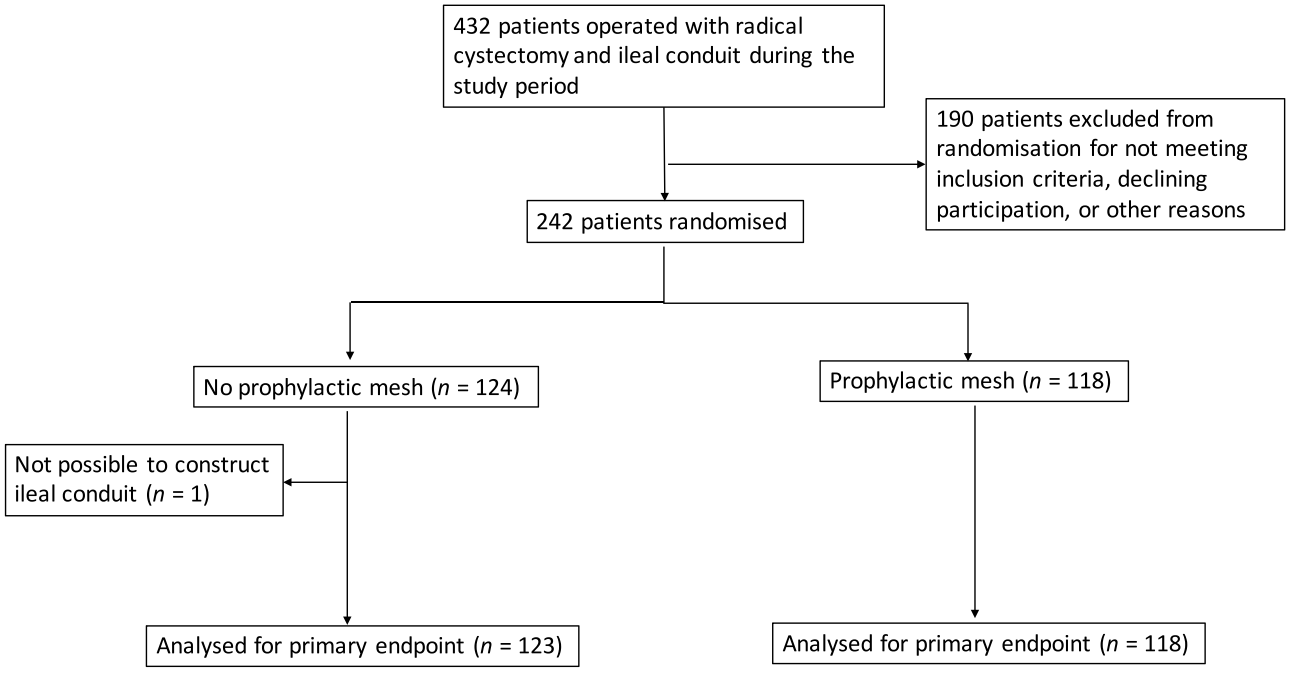

Fig. 1 – A CONSORT-diagram describing the study population.

Table 1 – Pre- and intraoperative patient and treatment characteristics shown by study arm.

	No mesh (n = 123)	Mesh (n = 118)
Preoperative characteristics		
Age (yr), median (IQR)	71 (66–76)	71 (65–74)
Gender, n (%)		
Male	97 (79)	91 (77)
Female	26 (21)	27 (23)
Operating hospital, n (%)		
Skåne University Hospital	47 (38)	50 (42)
Helsingborg County Hospital	40 (33)	35 (30)
Örebro University Hospital	36 (29)	33 (28)
ASA score, n (%)		
1	14 (12)	14 (12)
2	73 (61)	67 (57)
3–4	33 (28)	37 (31)
Missing	3	–
Smoking status, n (%)		
Nonsmoker	34 (29)	39 (36)
Previous smoker	62 (53)	44 (40)
Current smoker	20 (17)	27 (25)
Missing	7	8
BMI, median (IQR)	26 (24–28)	26 (22–28)
Previous inguinal hernia repair, n (%)		
No	109 (91)	107 (91)
Yes	11 (9)	11 (9)
Missing	3	–
Current inguinal hernia, n (%)		
No	114 (95)	114 (97)
Yes	6 (5)	4 (3)
Missing	3	–
Previous midline laparotomy, n (%)		
No	115 (97)	112 (98)
Yes	4 (3)	3 (3)
Missing		
Neoadjuvant or induction chemotherapy, n (%)		
No	78 (63)	66 (56)
Yes	45 (37)	52 (45)
Intra- and postoperative characteristics		
Adjuvant chemotherapy, n (%)		
No	116 (94)	110 (94)
Yes	7 (6)	7 (6)
Extent of lymphadenectomy, n (%)		
Aortic bifurcation	27 (22)	33 (28)
Iliac bifurcation	86 (70)	74 (63)
Obturator fossa/none	10 (8)	11 (9)
Primary urethrectomy, n (%)	35 (28)	24 (21)
Perioperative bleeding (ml), median (IQR) ml	500 (325–800)	450 (300–700)
Suture to wound length ratio, median (IQR)	5 (4–6)	5 (4–6)
Operation time (min), median (IQR)	365 (305–450)	415 (340–480)
Highest Clavien-Dindo grade complication at 90 d, n (%)		
1–2	19 (15)	21 (18)
3–5	30 (24)	32 (27)

ASA = American Society of Anesthesiologists; BMI = body mass index; IQR = interquartile range.

Table 2 – Number of patients with a clinical parastomal hernia out of all assessed patients at three time points (6, 12, and 24 mo).

	No mesh (n = 123)	Mesh (n = 118)
Clinical parastomal hernia within 6 mo	5/117	1/111
Clinical parastomal hernia within 12 mo	9/103	7/100
Clinical parastomal hernia within 24 mo	20/89	10/92

The denominators in the table are all patients alive at the time points reported.

Four patients in the control arm and three in the intervention arm developed a midline incisional hernia.

4. Discussion

The prophylactic use of a lightweight mesh in the sublay position decreased the proportion of clinical PSHs within 24 mo from 23% to 11%, corresponding to a relative risk of 0.45 (CI 0.24–0.86) at 3-yr median follow-up. During follow-up, surgery for PSH was performed in five patients in the

Table 3 – Clinical and radiological PSH shown by study arm (chi-square test).

	No mesh (n = 123)	Mesh (n = 118)	p value
Clinical parastomal hernia			
Yes	26	12	
No	97	106	0.03
Radiological parastomal hernia			
III	16	7	
I–II	12	9	
0	95	102	0.1

PSH = parastomal hernia.

control arm but in only two in the intervention arm. The proportion of Clavien-Dindo grade 3–5 complications within 90 d after surgery was similar in the two study arms, and no mesh-related complications were noticed at long-term follow-up. In a multivariable Cox proportional hazard analysis, use of a prophylactic mesh (HR 0.49 [CI 0.26–0.95]), BMI (HR 1.08 per unit [CI 1.01–1.16]), and surgery in one of the hospitals (HR 3.34 [CI 1.39–8.06]) were associated with the risk of PSH.

We have performed the only randomised study thus far to evaluate the use of a prophylactic mesh when constructing an ileal conduit. One of the limitations of the investigation is the lack of information on how the selection of patients was performed, that is, data specifically showing how many of the screened patients were considered ineligible for the study or denied participation and the characteristics of these patients compared with the randomised cohort. Furthermore, our study was not blinded, and the strategy of adding anterior fixation of the conduit to the rectus sheath in both study arms could be questioned when considering the hypothesis-generating findings reported in a recently published retrospective study [15]. Inasmuch as robotic-assisted laparoscopic cystectomy was not included in the present study protocol, the findings cannot be generalised to the robotic setting, even if it is possible to place a sublay mesh in such patients when performing minimally invasive radical cystectomy and ileal conduit [16]. Another limitation of our investiga-

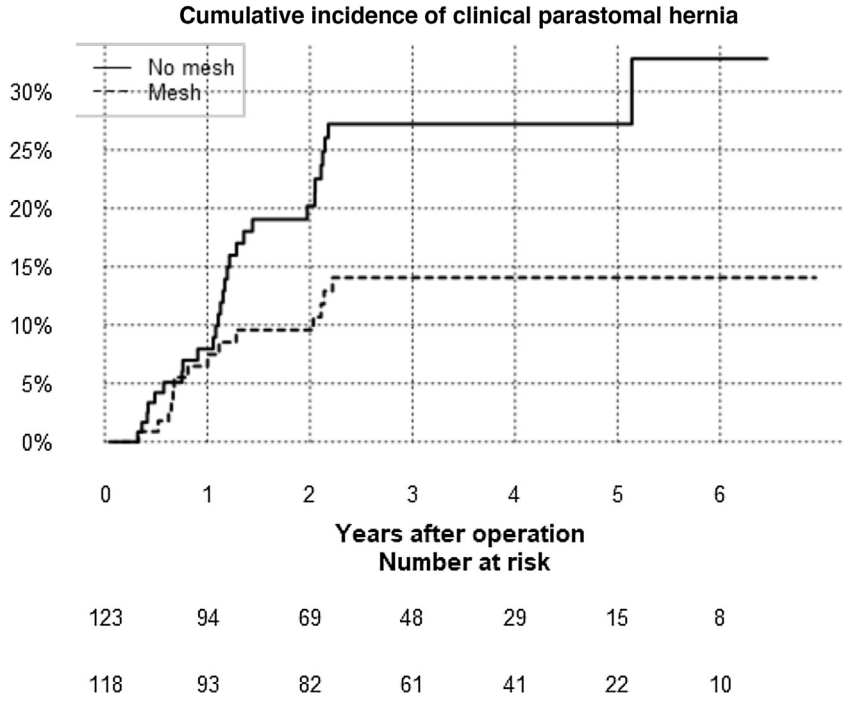

Fig. 2 – Cumulative incidence of clinical parastomal hernia (HR 0.45 [CI 0.24–0.86, p = 0.02]). CI = confidence interval; HR = hazard ratio.

Table 4 – Distribution of Clavien grade 3–5 complications 90 d after surgery between the study arms (Fischer's exact test).

Number of patients with Clavien-Dindo grade 3–5 complications at 90 d after surgery	No mesh (n = 31)	Mesh (n = 31)	p value
Wound dehiscence	8	3	0.2
Stenosis or insufficiency in ureterointestinal anastomosis	6	5	1.0
Insufficiency in the enteroenteroanastomosis	3	2	1.0
Lymphocele treated with percutaneous drainage	3	5	0.5
Postoperative bleeding with reoperation	1	1	1.0
Postoperative infection (unspecified)	5	3	0.7
Cardiovascular or thromboembolic events	1	2	0.6
Other causes of Clavien-Dindo grade 3–5 complications	4	10	0.1

tion is the intermediate length of follow-up, because progression of hernia size occurs in one out of three patients [13,17], and a longer follow-up might have added further PSH events taking into account that PSHs have been reported up to 27 yr after surgery [18]. In this context, the diminishing number of patients at risk during follow-up is another study limitation, as are the over-representation of individuals with older age, lower BMI, and more severe comorbidity among individuals without any information about the primary outcome clinical PSH beyond 24 mo of follow-up (Supplementary Table 4). This leads to an underestimation of the risk of PSH in a healthier population than in the present study, although not affecting the primary outcome measure as the mortality is distributed equally between the study arms.

The low rate of mesh-related complications observed in the present study is similar to the findings reported by other investigators [7,8]. However, one of the patients operated for a PSH in the control arm received a sublay lightweight mesh at surgical repair, and that patient suffered from erosion of the mesh into the conduit, which required a surgical revision. The rate of PSH of 23% within 24 mo in the control arm of the present study resembles that reported in the literature [4], although many published studies have not considered time-to-event analyses. The lack of valid assessment tools to investigate stoma and peristomal complications [19] is also problematic when analysing our results, together with a lack of several factors that might affect the healing process postoperatively such as diabetes mellitus and immunosuppression, both regarding the risk of PSH and mesh-related complications.

The effect size of the intervention in our study was smaller than that in a recent systematic review evaluating the use of a prophylactic sublay mesh when constructing stomas in general surgery [6], which demonstrated 37% PSH in the control arm but only 16% PSH in the intervention arm (odds ratio 0.24 [CI 0.12–0.50]). However, generalisation of the outcome of the present study and recommendation of a prophylactic mesh in all patients receiving an ileal conduit must be balanced against the longer operating time. However, it is also possible that a larger effect size with more events can occur during longer follow-up and that proper health-economic analyses can add information to the decision regarding whether to use a prophylactic mesh when constructing an ileal conduit. Some institutions have already been using a prophylactic sublay mesh in obese and female patients when performing ileal conduits [8], and this seems relevant when considering the outcome of the present study—an 8% increased risk of PSH per increased BMI unit was noted in the present study. The knowledge that ileal conduit formation in women with incontinence might also be associated with an increased risk of PSH further supports the use of a prophylactic mesh in these patients [20]. On the contrary, the evolution of new less extensive procedures to repair PSHs that obviate the need for a laparotomy [21] must also be weighed into the decision of whether a prophylactic mesh should or should not be used.

5. Conclusions

The use of a prophylactic lightweight mesh reduces the risk of PSH after ileal conduit construction without causing any mesh-related complications, although with a prolonged operating time. Especially in obese patients who are at risk for developing PSHs, such a prophylactic measure can be recommended based on the present results; however, with longer follow-up and health-economic analyses, the use of a prophylactic mesh at surgery can be defined further.

***Author contributions*:** Fredrik Liedberg had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Liedberg, Kollberg, Baseckas, Brändstedt, Gudjonsson, Håkansson, Patschan, Bläckberg.
Acquisition of data: Liedberg, Kollberg, Allerbo, Baseckas, Brändstedt, Gudjonsson, Hagberg, Håkansson, Jerlström, Löfgren, Sörenby, Bläckberg.
Analysis and interpretation of data: Liedberg, Kollberg, Allerbo, Baseckas, Brändstedt, Gudjonsson, Hagberg, Håkansson, Jerlström, Löfgren, Sörenby, Bläckberg.
Drafting of the manuscript: Liedberg, Kollberg, Allerbo, Baseckas, Brändstedt, Gudjonsson, Hagberg, Håkansson, Jerlström, Löfgren, Patschan, Sörenby, Bläckberg.
Critical revision of the manuscript for important intellectual content: Liedberg, Kollberg, Baseckas, Brändstedt, Gudjonsson, Hagberg, Håkansson, Jerlström, Patschan, Sörenby, Bläckberg.
Statistical analysis: Liedberg, Hagberg, Kollberg, Bläckberg.
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Supervision: Liedberg, Bläckberg.
Other: None.

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Appendix A. Supplementary data

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