Guidelines for Vulvar and Vaginal Surgery: Enhanced Recovery After Surgery (ERAS) Society Recommendations

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# Guidelines for Vulvar and Vaginal Surgery: Enhanced Recovery After Surgery (ERAS) Society Recommendations

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33

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## 35 Abstract:

36

37	This is the first collaborative Enhanced Recovery After Surgery (ERAS) Society guideline for
20	ontimel perioperative care for vulver and veginal surgery. An Embase and Pubmed detabase
20	optimal perioperative care for vurvar and vaginar surgery. An Embase and I ubmed database
39	search of publications was performed. Studies on each topic within the ERAS vulvar and vaginal
40	outline were selected, with emphasis on meta-analyses, randomized controlled trials and
41	prospective cohort studies. All studies were reviewed and graded according to the Grading of
42	Recommendations, Assessment, Development and Evaluation (GRADE) system. All
43	recommendations on ERAS topics are based on best available evidence. The level of evidence
44	for each item is presented.
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### 56 Introduction

- Enhanced Recovery After Surgery (ERAS) is regarded as a global surgical quality improvement 57 initiative that results in clinical <sup>1</sup> and cost benefits.<sup>2</sup> The ERAS Gynecologic/Oncology 58 guidelines <sup>3,4</sup> were first published in 2016 and updated in 2019.<sup>5</sup> The ERAS gynecology 59 protocols to date, however, have focused mainly on intraabdominal surgery, with no 60 recommendations for vulvar and vaginal surgery, often performed in the oncology and 61 62 urogynecology settings, respectively. To address this gap, the ERAS Society Gynecology chapter convened to critically review existing evidence and make recommendations for elements of pre-, 63 intra- and post-operative care as it relates to vulvar and vaginal surgery. 64
- 65

## 66 Methods

### 67 *Literature search*

The guideline was developed according to published methodology from the ERAS Society.<sup>6</sup> 68 The authors convened in September 2019 to discuss topics for inclusion – the topic list was 69 based on the ERAS Gynecologic/Oncology Guidelines <sup>3–5</sup> which were used as a template, and 70 expanded to include topics unique to vulvar and vaginal surgery. The topics were then allocated 71 amongst the group according to expertise. The literature search used Embase and PubMed to 72 search medical subject headings between 1975-2020, including "gynecology", "gynecologic 73 oncology", "urogynecology" and all pre-, intra- and post-operative ERAS items (see Table 1). 74 Reference lists of all eligible articles were crosschecked for other relevant studies. Meta-75 analyses, systematic reviews, randomized controlled trials (RCT), nonrandomized controlled 76 studies, reviews, and case series were considered for each individual topic. Two to three authors 77

reviewed the evidence base for each item. The quality of evidence for each item was then 78 reviewed and crosschecked by the senior editorial team (AA, GN and SD). The final manuscript 79 was then reviewed by all authors to assess quality of evidence and relevant studies for final 80 inclusion; all papers that were examined for inclusion are listed in the supplemental appendix 81 (Supplement #1). The search strategy was focused on relevant papers and supplemented by 82 expert citation searches to identify further important studies. The purpose of the search strategy 83 and guideline formation was not to obtain a comprehensive summary of all literature, but to 84 ensure that the most important and current work is highlighted.<sup>6</sup> 85

86

### 87 Quality assessment

The quality of evidence and recommendations were assessed based on the GRADE (Grading of 88 Recommendations, Assessment, Development and Evaluation) system, <sup>7</sup> presented in Table 2 as 89 per previous guidelines.<sup>3–5</sup> Each study included was assessed according to GRADE criteria and 90 the final list of referenced studies was decided upon by the guideline development group; 91 although not all papers are referenced in the final product, the studies chosen are representative 92 of the best quality of evidence with the broadest scope of application.<sup>6</sup> Recommendations are 93 based on the level of evidence as high, moderate and low, equalized by desirable and deleterious 94 effects. Strong recommendations mean that the ERAS group felt that the advantages of the 95 recommendations outweighed the risks, whereas a weak recommendation indicates that the 96 group felt that the advantages likely outweigh the risk, but felt less confident in the overall 97 strength of evidence. As such, there may be cases in which strong recommendations are reached 98 from low evidence data, and weak recommendations from strong evidence data. 99

#### **Results** 101

The recommendations, evidence level and recommendation grade are provided for each of the 102 individual ERAS elements in Table 1, with summary descriptions of the evidence below with the 103 associated level of evidence in brackets. 104

105

#### Preadmission information, education and counselling 106

The goal of preoperative education is to physically prepare the patient for surgery, but also to 107 prepare them for what to expect after surgery. Preoperative preparation allows patients to better 108 understand the procedure, feel more in control, experience decreased postoperative pain and 109 anxiety, and can even reduce length of hospital stay.<sup>8</sup> 110

111

Information may be provided in many forms: verbal, written or multimedia, and should be 112 adapted to cultural and social aspects. Written information was found to be superior to verbal 113 alone in one randomised trial for satisfaction, days of hospitalization and pain.<sup>9</sup> However the 114 addition of an education video for pelvic reconstructive surgery did not improve patient 115 preparedness for surgery.<sup>10</sup> 116

117

#### Recommendation: 118

While there is limited evidence in this field, most studies from other specialities provide 119

evidence of beneficial effects and no evidence of harm. It is therefore recommended that patients 120

should routinely receive dedicated pre-operative information, education and counselling (Low). 121

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## 123 **Preoperative optimization**

In the past it has been postulated that since hair harbours bacteria, removal of hair should
decrease surgical site infection rates. A Cochrane review showed lack of evidence supporting
hair removal, however there were no specific studies examining removal of pubic hair.<sup>11</sup> A
small study comparing perineal shaving to no hair removal showed no difference in infection
rates.<sup>12</sup> However, if pubic hair is removed to improve visualization of the surgical field, clipping
should be used over shaving to reduce the rate of surgical site infections.<sup>11</sup>

130 The use of preoperative vaginal estrogen in postmenopausal women has been shown to increase

the maturation index and vaginal epithelial thickness but there is lack of evidence that this

translates to improved outcomes in prolapse surgery.<sup>13</sup> An RCT using vaginal estrogen prior to

and one year following vaginal prolapse surgery with mesh found no estrogen to be noninferior

to estrogen therapy when examining mesh erosion and anatomical success as endpoints.<sup>14</sup>

## 135 <u>Recommendation:</u>

Routine removal of pubic hair for vulvar surgery does not decrease infection rates (Low). If hair
is removed, it should be clipped and not shaved (High). There is little evidence to support use of
preoperative vaginal estrogen in postmenopausal women to decrease postoperative complications
(Low).

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### 141 **Preoperative bowel preparation**

Traditionally mechanical bowel preparation (MBP) in gynecologic surgery, especially in
anticipation of potential bowel resection, was believed to decrease the risk of anastomotic leak
and prevent perioperative infectious morbidity.<sup>15</sup> In 2018, a meta-analysis of 21568 patients

145	undergoing colorectal surgery showed that MBP was not associated with any difference in
146	anastomotic leak rates, surgical site infection, intraabdominal collection, reoperation or hospital
147	length of stay, when compared with no MBP. <sup>16</sup> Similar conclusions were reached in a 2015
148	meta-analysis of 5 RCTs in gynecologic surgery. <sup>17</sup> There is limited data in vaginal surgery with
149	the exception of a recent RCT which showed that women who underwent MBP prior to
150	minimally invasive sacrocolpopexy demonstrated benefit to post-operative defecatory function
151	and improved surgeon's perceptions of the case. <sup>18</sup> Enemas, however do not appear to adversely
152	impact recovery or electrolytes, and may be useful to reduce the stool burden at the time of
153	vaginal or vulvar procedures, although no further data exists on rates of infection.
154	
155	Recommendation: Preoperative bowel preparation is not recommended before vulvar
156	(Moderate) and vaginal surgery (Low); enemas may be considered to reduce the stool burden at
157	the time of vaginal surgery.
158	
159	Prophylaxis against venous thromboembolism
160	The literature suggests the risk of venous thromboembolism (VTE) in vulvar and vaginal cancer
161	surgery is similar to that observed for patients undergoing surgery for other gynecologic
162	cancers. <sup>19</sup> Formulation of guidelines is complicated by wide variations in surgical complexity for
163	vulvar procedures, ranging from outpatient laser ablation and limited wide-local excisions, to
164	radical resections with inguinal lymphadenectomy, and potential reconstruction. In an evaluation
165	using the American College of Surgeons National Surgical Quality Improvement Program (ACS
166	NSQIP) database, the 30-day rate of DVT and/or pulmonary embolism (PE) was 1.2% in 497
167	patients undergoing surgery for vulvar cancer, compared to 3.0%, 1.4%, and 1.5% for ovarian,

cervical, and endometrial cancer, respectively.<sup>20</sup> However, less than a third of patients 168 undergoing vulvar resection had a concurrent inguinal lymphadenectomy, suggesting that many 169 of these patients had preinvasive or micro-invasive disease, and the VTE rate may therefore be 170 underestimated. A single institution study over a 10-year period reported on 219 patients with 171 vulvar and 141 with vaginal cancer (including resection for Paget's disease), only 5 of whom 172 were not comprehensively staged.<sup>19</sup> Perhaps due to a higher rate of lymphadenectomy or longer 173 follow-up, the rates of VTE were higher than reported in ACS-NSQIP, 3.7% for vulvar and 0.7% 174 for vaginal cancer. Patients were purported to have received prophylaxis with stockings and low 175 molecular weight heparin (LMWH) from 48 hours to 14 days postoperatively, but no assessment 176 of compliance was provided. 177

178

Patients undergoing surgery for vulvar or vaginal cancer should therefore receive dual VTE 179 mechanical prophylaxis and chemoprophylaxis with either LMWH or unfractionated heparin 180 (UFH), to begin before the induction of anesthesia as recommended by the American Society of 181 Clinical Oncology (ASCO).<sup>21</sup> Dual prophylaxis should continue throughout the hospital stay. In 182 keeping with ASCO recommendations, procedures lasting >30 minutes should be managed as 183 described above. In contrast to patients with advanced ovarian cancer, the residual tumor burden 184 for patients with vulvar and vaginal cancer is quite low; no data exists for prolapse or benign 185 procedures. For this reason, it is premature to recommend routine extended prophylaxis for these 186 patients, although may be considered in elderly, frail and immobile patients depending on their 187 Caprini scores.<sup>22</sup> 188

189

In benign vaginal surgery, the data continue to be limited as well. In a large retrospective analysis of NSQIP data, 26,103 women who underwent surgery for pelvic organ prolapse were evaluated for VTE; 81.7% had a vaginal approach. The overall rate of VTE in this population was < 1% for all groups, with the vaginal group having the lowest rate of 0.17% (p<0.01).<sup>23</sup> A second similar study for 20,687 women with pelvic reconstructive surgery showed a rate of VTE of 0.1%.<sup>24</sup>

196

197 <u>Summary and Recommendation:</u>

Patients undergoing procedures lasting >30 min should receive dual mechanical prophylaxis and
chemoprophylaxis with either LMWH or UFH for cancer surgery (Moderate). Prophylaxis
should be initiated pre-operatively and continued throughout the hospital stay for malignant
surgery (Vulva – Moderate; Vaginal – Low). In benign vaginal and vulvar surgery, the rates of
VTE are very low, but prophylaxis may still be considered (Low). Studies on extended
postoperative prophylaxis are needed in vulvar/vaginal surgery for both malignant and benign
indications (Low).

205

## 206 Antimicrobial prophylaxis

It is well established that patients undergoing vaginal hysterectomy, like abdominal
hysterectomy, should receive single-dose antimicrobial prophylaxis within 1 hour of incision.<sup>25</sup>
A Cochrane review showed that compared with placebo, women who received antimicrobial
prophylaxis for vaginal hysterectomy had a reduction in total postoperative infections, including
urinary tract infections.<sup>26</sup>

212	For patients undergoing vaginal surgery without hysterectomy, such as with anterior or posterior
213	colporrhaphy, the evidence for antimicrobial prophylaxis is less clear. While theoretically there
214	could be benefit from prophylaxis in these cases given that they are classified as clean-
215	contaminated, at the present time there is insufficient evidence to make concrete
216	recommendations, thus the decision is left up to the discretion of the surgeon. <sup>27</sup> Although this
217	appears to be similar for patients having vaginal surgery with the use of mesh (e.g. midurethral
218	sling) where infection rates are very low, <sup>28,29</sup> 93% of surgeons said they administered some form
219	of antibiotic prophylaxis when graft material was used in prolapse surgery. <sup>30</sup>
220	Vulvar procedures such as vulvectomy which are typically performed for cancer are associated
221	with a high risk of infection. Radical vulvectomy has a surgical site infection rate (SSI)
222	comparable to that of patients undergoing abdominal hysterectomy with a type IV wound. <sup>31,32</sup>
223	Like vaginal surgery without hysterectomy, there is no randomized evidence supporting
224	antimicrobial prophylaxis in this setting. However, given the high rate of SSI it seems reasonable
225	to give a single dose of antibiotic, consistent with other published guidelines. <sup>25</sup>
226	Recommendation:
227	IV antibiotics should be administered routinely within 60 min before vaginal hysterectomy
228	(High). IV antibiotics should be considered for vaginal surgery without hysterectomy (Low) and
229	vulvar procedures (Low), particularly radical vulvectomy (contaminated wound), where SSI

230 rates are high.

231

## 232 Standard anesthetic protocol and fluid management

233 The anesthetic protocol for patients undergoing major vulvar and vaginal surgery is conducted

with the aim of providing anesthesia that reduces the surgical stress response, provides analgesia,

and encourages the rapid return of mobilization, eating, and drinking. In addition, postoperative
nausea and vomiting (PONV) with multimodal prophylaxis in this high-risk group of patients is
required. Extremes of fluid balance and organ dysfunction should be avoided.<sup>33,34</sup>

238

For many patients either general and/or regional anesthesia can be used; there is little evidence to 239 recommend one technique over the other. If general anesthesia is chosen, maintenance can be 240 241 provided with either a volatile-based approach or total intravenous anesthesia (TIVA). Nitrous oxide is not recommended due to increased nausea and vomiting.<sup>35,36</sup> There is much enthusiasm 242 for TIVA over a volatile anesthesia as it reduces the incidence of PONV and in those patients 243 with malignancy may improve long term survival.<sup>37</sup> If TIVA is used, processed EEG monitoring 244 (eg Bispectral Index) is recommended to ensure appropriate depth of intraoperative anesthesia, 245 permitting rapid return of consciousness.<sup>38</sup> If neuromuscular (NM) blocking drugs are 246 employed, then complete reversal of NM function must be confirmed at the end of the procedure 247 with objective NM monitoring. The use of protective mechanical ventilation with tidal volume 248 6-8 ml/kg and the use of positive end expiratory pressure (PEEP) may be of benefit.<sup>5</sup> 249

250

Regional anesthesia (such as intrathecal or epidural) can provide excellent intraoperative and postoperative analgesia. However, side-effects such as motor block, hypotension, and urinary retention limit their postoperative use. If an epidural catheter has been used, it should be discontinued soon after surgery as analgesic requirements are generally modest. There is little evidence to support other modalities such as ketamine, lidocaine, alpha-2 agonists and pregabalin although some advocate the use of these drugs if undertaking opioid free anesthesia to reduce the problems associated with opioids, particularly opioid tolerance and opioid-induced

258	hyperalgesia. <sup>39</sup> Three small RCTs have shown efficacy of preemptive paracervical block in
259	patients undergoing vaginal hysterectomy. <sup>40,41</sup> A number of series have indicated that local
260	anesthesia with sedation can be successfully employed for vaginal prolapse surgery. <sup>42</sup>
261	
262	Fluid management should be directed towards replacing intraoperative blood loss whilst aiming
263	for euvolemia to avoid the problems associated with fluid overload (eg edema, ileus) or
264	hypovolemia (eg acute kidney injury). Maintenance of blood pressure once euvolemia is
265	achieved should be with vasoactive drugs to avoid fluid overload. The use of cardiac output
266	monitoring and/or goal directed therapy is not routinely recommended. <sup>43</sup>
267	
268	Recommendation:
269	The use of short-acting anesthetics (Low), monitoring of neuromuscular block depth and
270	complete reversal is recommended (High). Fluid balance should be directed with the goal of
271	euvolemia (Moderate). Preemptive analgesia is recommended for vaginal hysterectomy, and can
272	be considered for vaginal prolapse surgery (Moderate).
273	
274	Urinary drainage
275	Immediate postoperative voiding dysfunction is potentially a complication of most pelvic
276	surgeries. It is a particular problem for procedures targeting the urethra such as surgeries for
277	stress urinary incontinence. It is such a common issue that some centers routinely teach patients
278	how to perform clean intermittent self-catheterization as part of preoperative teaching. Following
279	stress incontinence surgeries such as midurethral sling, bladder emptying is assessed with a
280	voiding trial (VT). VT involves measuring voided volume followed by an assessment of the

281 post-void residual (PVR). There are multiple methods of filling the bladder before a VT that involves filling the bladder in the OR to a defined volume, retrograde catheter fill in the post-282 anesthesia care unit (PACU), or awaiting spontaneous bladder fill in the PACU. Foster et al. 283 performed a randomized trial evaluating bladder function after outpatient vaginal surgery and 284 found that patients were more likely to successfully void after a retrograde fill compared with 285 spontaneous bladder fill (61.5 vs 32.1% respectively, p = 0.02).<sup>44</sup> In a subsequent trial, Myers et 286 al. documented that retrograde filling the bladder in the OR rather than in the PACU was an 287 effective strategy for the postoperative voiding trial. However, this approach did not significantly 288 reduce total PACU time. In both studies the retrograde bladder fill method was demonstrated to 289 be more accurate, preferred by patients, and enabled women to be discharged from the PACU up 290 to 27 min earlier. 45 291

A small randomized prospective study examined catheterization in 100 women undergoing 292 vaginal hysterectomy, and found that catheterization after surgery was unnecessary, but there 293 were no increased complications if left in for 24 hours.<sup>46</sup> In women undergoing Burch 294 colposuspension, a randomized trial reviewed the removal of catheter postop day 1 vs 5, and 295 found no benefit for prolonged catheterization.<sup>47</sup> A randomized trial in patients undergoing 296 vaginal prolapse surgery, with removal of catheter postop day 1 vs 5, again found no benefit to 297 prolonged catheterization, with a higher rate of positive cultures, prolonged hospitalization and 298 increased re-catherization rate in the day 5 group.<sup>48</sup> A Cochrane review was performed in 2006 299 <sup>49</sup> on short term catheterization policies, and included 39 RCTs with a heterogeneous mixture of 300 surgeries including: vaginal or abdominal hysterectomy, anterior/posterior repairs, Burch 301 colposuspension and urological surgery; the length of catheterization also varied from 1-28 days. 302 The review found that not using a catheter had an increased risk of re-catheterization; similarly 303

urethral catheterization had a high risk of re-catheterization compared to a suprapubic approach
after removal.<sup>49,50</sup> In 11 trials, shorter catheterization resulted in lower rate of infections. Finally
using a clamp-release protocol resulted in a higher risk of infection and delay of normal urination
when compared to an immediate release policy.<sup>49</sup>

308

## 309 <u>Recommendation:</u>

Retrograde bladder filling for voiding trial should be considered in vaginal surgery since it 310 appears to be preferred by patients and may shorten time in the PACU (High). Urinary catheters 311 should be used for postoperative bladder drainage in complex vaginal surgery, but may be safely 312 eliminated in simple vaginal hysterectomy. Removal after a short period postoperatively appears 313 to be associated with lower rates of re-catheterization, bladder infection and length of stay 314 315 (Vaginal – High, Vulvar - Low). The suprapubic route is associated with a lower rate of bladder infection but higher rate of catheter related complications, and may be considered if a prolonged 316 catheterization is expected. There remains insufficient data on urinary drainage in vulvar surgery. 317

318

## 319 **Postoperative analgesia**

320

Patients presenting with vulvar and vaginal abnormalities requiring surgical resection frequently complain of pain, particularly those with ulcerative/malignant lesions may already be receiving preoperative analgesics and are often anxious about control of their postoperative pain. However, removal of the lesion usually reduces pain significantly, even when large resections are needed, and postoperative pain control is rarely problematic. Published studies evaluating optimal control

of postoperative pain in patients undergoing vulvar procedures are nonexistent, but the paradigm
of multimodal, opioid-sparing post-operative analgesia used commonly within ERAS pathways
should also be used for these patients too.<sup>51</sup> In addition the postoperative strategy should be
reviewed with patients prior to surgery to aid optimal pain control and functional recovery, yet
minimize nausea, sedation, fatigue and risk of opioid addiction.<sup>52</sup>

331

The use of preoperative oral acetaminophen and an anti-inflammatory drug (if not 332 333 contraindicated) has been shown to reduce opioid requirements and should be a routine element in all ERAS pathways.<sup>53,54</sup> Since patients undergoing vulvar procedures, particularly patients 334 with vulvar cancer, tend to be elderly, anti-convulsant medications and chronic pain drugs should 335 not routinely be used in the post anesthesia care unit.<sup>55,56</sup> The use of local anesthetic medication 336 may be feasible into the wound edges, but its use in regional anesthetic techniques e.g. caudal 337 epidural anesthesia is not advocated, as it may be associated with post-operative problems such 338 as hypotension and urinary retention for vulvar procedures. For vaginal surgery, there is some 339 support for using local anesthetics, especially for paracervical and vaginal cuff blocks;<sup>54,57</sup> 340 liposomal bupivacaine may be helpful, but still requires further study.<sup>54,58</sup> Postoperatively, 341 patients should receive scheduled oral acetaminophen and ibuprofen, oral opioids as needed, and 342 intravenous opioids for breakthrough pain. Given the rarity of severe pain in this population, 343 patients with breakthrough pain should be carefully evaluated for infections, wound breakdown 344 or other complications. Patients who do not require opioids in hospital, will not require home-345 going opioid prescriptions and should be counseled to continue scheduled ibuprofen and 346 acetaminophen. For patients requiring home-going opioids, we recommend a prescription for the 347

- 348 minimum duration e.g. 10 tablets of oxycodone, 5mg in order to minimize the risk of opioid
   349 dependence and diversion.<sup>59</sup>
- 350

351 <u>Recommendation:</u>

A multimodal post-operative analgesic protocol should be used routinely, and home-going opioidprescriptions should be minimized (High).

354

## 355 **Preoperative and postoperative nutrition**

356 Historically, surgical patients have been subjected to the "NPO after midnight" rule

preoperatively with no supporting evidence. In fact, adoption of modern fasting rules whereby a
patient is allowed to have a light snack up until 6 h, and clear fluids (including oral carbohydrate
drinks) up until 2 hours prior to surgery has been shown to be safe <sup>60</sup>. Furthermore,

360 administration of oral carbohydrates preoperatively is associated with improved pre-operative

361 well-being, and reduced post-operative insulin resistance.<sup>61</sup> There remain no specific trials in

vulvar or vaginal surgery, but the underlying principles from laparotomy can be broadly adopted

363 here until further research is completed.

364 Similarly, in the past it was common practice to withhold food from postoperative patients until

365 passage of flatus. Early feeding, whereby nutrition is introduced within 24 hours post-

366 gynecologic surgery, has been shown to be safe without increased gastrointestinal concern or

367 postoperative complications.<sup>62</sup> This approach is associated with earlier return of bowel function,

368 shorter length of hospital stay, and improved patient satisfaction. A number of studies have now

369 successfully and safely incorporated these perioperative nutritional practices into their

## 370 urogynecologic ERAS protocols. Lastly, there is little concern for ileus in patients undergoing vulvar or vaginal surgery,<sup>63,64</sup> which further strengthens an early refeeding approach. 371 372 **Recommendation:** Patients should be encouraged to eat a light snack up until 6 hours, and clear fluids (including 373 oral carbohydrate drinks) up until 2 hours prior to initiation of anesthesia (High). A regular diet 374 within the first 24 hours after vaginal/vulvar surgery is recommended based on extrapolation 375 376 from larger more invasive procedures (Moderate by indirectness). 377 378 **Postoperative Dressing care** 379 Vaginal packing is thought to decrease postoperative vaginal and vault hematoma formation and 380 381 consequently decrease infection rates in prolapse surgery. However, it has been suggested that packing also increases pain, prolongs hospitalization and can lead to leaving packing 382 accidentally in place, resulting in retained "foreign objects". Recent trends have been to use 383 vaginal packing for 24 hours postoperatively,<sup>65</sup> which requires indwelling catheterization. One 384 RCT involving 190 women examined outcomes at 24 hours post-operatively for patients packed 385 with proflavine soaked cotton gauze versus no packing, and found no difference in pain scores, 386 infectious morbidity or hematoma formation (7.3 % in pack group vs 14.8 % in no pack group p 387 =0.204).<sup>66</sup> A second small RCT showed similar pain on a visual analog scale (VAS) but less use 388

of ketorolac in the first 24 hours and nursing reported pain in the packing group.<sup>67</sup> Two RCT's
investigated length of time for packing and found no difference between 3h and 24h; there was

391 no difference in febrile morbidity and complications, but shorter packing was associated with

392 non-significantly higher urinary retention rates.<sup>68,69</sup>

Although no specific research has been done for patients undergoing laser of the vulva, several

studies have examined the role of occlusive dressings after laser skin resurfacing. A small 394 retrospective study of open wound care compared to perforated silicone occlusive dressing found 395 a decrease in the rate of erythema, swelling and crusting.<sup>70</sup> Occlusive dressings may promote re-396 epithelialization and improve wound healing by creating a moist environment.<sup>71–73</sup> 397 Vacuum Assisted Closure (VAC) dressings have also occasionally been used for closure of 398 radically excised perineal and vulvar wounds.<sup>73–80</sup> One investigation retrospectively examined 399 54 patients with VAC compared to standard postoperative care in patients after radical excisions 400 and found a decrease in time to complete healing (44.4 vs 60.2 days; p=0.0175).<sup>80</sup> Another 401 group retrospectively assessed 24 patients with penile or urethral cancer requiring 402 inguinofemoral lymph node dissections and found decreased rates of hospitalization, 403 lymphocele, persistent lymphorrhoea and lymphedema with use of VAC.<sup>81</sup> Contamination with 404 405 stool and urine must be avoided when VAC dressings are applied to the vulva and perineum; immediate treatment solutions have included use of foley catheters, antimotility agents (e.g. 406 Imodium and Codeine), rectal tubes and waterproof dressings (e.g. Duoderm).<sup>75,77</sup> VAC 407 dressings have also been used in complicated inguinal incisions.<sup>73,78,82–84</sup> Although it continues to 408 be common practice, there are no high-quality studies examining the utility of silver sulfadiazine 409 cream after laser vaporization of the vulva. 410

411 <u>Recommendation:</u>

393

Vaginal packing does not appear to decrease post-operative bleeding and hematoma formation or
increase postoperative pain (High). Vaginal packing may result in an increase in postoperative
infection rates when left for longer than 24 hours (Low) and longer use of packing results in

415 longer catheterization, and thus higher rates of UTI. Occlusive dressings may be used post-laser416 to promote healing (Low).

417

## 418 **Postoperative drains and adjuvant therapies**

Postoperative drains after systematic inguino-femoral lymph node (IFLN) dissection are used 419 routinely and often left in situ until producing < 20-50 ml/24 hours,<sup>85–89</sup> with some 420 recommendations to leave the drains in place at least 5-7 days postoperatively.<sup>73,90,91</sup> This is 421 422 thought to decrease lymphocyst formation by allowing the overlying skin flaps to adhere to the underlying connective tissue.<sup>85</sup> Separate vulvar drainage has been abandoned by most.<sup>32</sup> 423 424 Adjuvant products such as fibrin sealant and albumin-glutaraldehyde adhesive have not been proven to decrease morbidity.<sup>73,92–94</sup> Preservation of the saphenous vein appears to reduce the 425 rate of lymphedema, cellulitis, and dehiscence.95 426

427 Multiple retrospective studies have investigated time-based or volume-based IFLN drainage to guide drain removal, with no definitive conclusions. Overall, short duration of use (<3 days) was 428 associated with higher rates of wound breakdown, while longer duration of use (>7 days) was 429 associated with higher rates of lymphedema.<sup>86</sup> Drain use has also been shown to have higher 430 rates of cellulitis.<sup>96</sup> Another investigation showed that higher drain output on the final day 431 before removal was a risk factor for complications, including lymphocele formation.<sup>91</sup> Two 432 prospective studies demonstrated that removal once output had decreased to <30-50cc/day 433 resulted in lower rates of lymphocele formation and other complications. No prospective studies 434 have evaluated drainage after inguinal sentinel lymph node biopsy in women with vulvar cancer. 435 There were no studies examining the role of surgical drains for vaginal or prolapse surgery. 436 Novel postoperative therapies: 437

Routine postoperative vulvar care for radical vulvar excisions, often consists of irrigation and

perineal drying with either a hair dryer or vulvar blower/fan.<sup>73,80</sup> However, no studies have been 439 identified showing efficacy for this practice. 440 A small RCT was performed on granulocyte colony-stimulating factor (G-CSF) versus placebo 441 in 40 vulvar cancer resection patients based on an earlier retrospective study.<sup>97</sup> The authors 442 found no difference in rates of wound infection between the groups, with increased cost 443 associated with G-CSF. Adjuvant platelet gel has been studied in a retrospective study <sup>98</sup> applied 444 to the vaginal resection portion of the radical vulvectomy; the platelet gel group had significantly 445 less wound complications; no prospective or randomized trials have been performed. 446 Hyperbaric oxygen (HBO) has been used to improve tissue oxygenation, thereby stimulating 447 healing and angiogenesis. Investigation of HBO in radical vulvectomy patients showed 448 significantly less wound breakdown compared to historic controls (p=0.0105).<sup>89,99</sup> Although a 449 very promising treatment that is commonly utilized, further trials must be performed to 450 demonstrate efficacy of this expensive therapy. 451 Zinc has been shown to be necessary for the early stages of repair, and oral supplementation is 452 thought to restore sub-clinically low levels. A pilot study investigated zinc sulfate 220 mg orally 453 three times daily for 7 days preoperatively in patients undergoing radical vulvectomy and 454

455 lymphadenectomy. The authors showed a decreased rate of wound dehiscence and a reduced
456 hospital stay from 37 to 18 days.<sup>73</sup>

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458 <u>Recommendation:</u>

- 459 Drainage of inguinal lymph node dissection should continue until < 30-50 cc/day of drainage</li>
  460 (Moderate). Saphenous vein preservation should be considered in IFLN dissection (Moderate).
- 461

## 462 <u>Comment:</u>

This guideline summarizes current evidence examined by the ERAS Society Gynecology chapter 463 on recommendations for elements of pre-, intra- and post-operative care in vulvar and vaginal 464 465 surgery. In several instances, where good quality data were not available, recommendations were made based on other surgical disciplines and the original Gynecologic/Oncology ERAS 466 guidelines. The ERAS gynecology committee decided to combine vulvar and vaginal surgery 467 468 since these are common approaches in practice for general gynecology and subspecialities including urogynecolgy and gynecologic oncology. The authors felt that the peri-operative care 469 for both was similar, and differences have been highlighted in the sections above. Since ERAS 470 471 guidelines are created by reviewing all current and updated literature, including systematic reviews, metanalyses, RCTs, retrospective studies and studies in similar disciplines, it does not 472 follow the same process as a systemic review of looking at only specialty specific randomized 473 trials. The advantages of this process include using any relevant information that is currently 474 available, which is then reviewed by an international panel of experts. The disadvantages are 475 that some of the recommendations are based on expert opinion and low levels of evidence. 476

477

This guideline summarizes the best evidence in common practices for vulvar and vaginal surgery
but recognizes the paucity of evidence specific to this area in topics such as ileus prevention,
postoperative diet and mobilization. We hope that these guidelines will help expand ERAS

- 481 protocols into gynecologic surgeries outside of the realm of laparotomy/laparoscopy, helping
- 482 improve patient outcome, optimize hospital stay and reduce systemic costs.
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800	Table 1 Guidelines for Vulvar and Vaginal surgery Enhanced Recovery After Surgery (ERAS)
801	Society Recommendations
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## 842 Table 2:

- 843 Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system
- rating of quality and strength of evidence

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Journal Prevention

#### Supplement 1: Reference list of all articles examined for the review of the ERAS guideline

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ITEM	RECOMMENDATION	EVIDENCE LEVEL		RECOMMENDATION	N GRADE	
		Vulvar	Vaginal	Vulvar	Vaginal	-
PREADMISSION INFORMATION, EDUCATION AND COUNSELLING	Patients should routinely receive dedicated pre- operative information, education and counselling.	Low	Low	Strong	Strong	Table 1
PREOPERATIVE OPTIMIZATION	Routine removal of pubic hair should not be used to decrease infection rates	Low	n/a	Strong	n/a	Guidel ines for Vulvar
	clipped and not shaved	High	n/a	Strong	n/a	and Vagin al
	Use of preoperative vaginal estrogen in postmenopausal women decreases postoperative complications	n/a	Low	n/a	Weak	surger y Enhan
						ced Recov ery After Surger Y (ERAS) Societ Y Reco mmen dation s

PREOPERATIVE BOWEL PREPARATION	Preoperative bowel preparation should not be used before vulvar and vaginal surgery	Moderate	Low	Strong	Weak (may consider enema to reduce stool burden)
PROPHYLAXIS AGAINST THROMBOEMBOLISM	Patients undergoing malignant procedures lasting >30 min should receive dual mechanical prophylaxis and chemoprophylaxis with either low molecular weight heparin or unfractionated heparin.	Moderate	Moderate	Strong	Strong
	Prophylaxis should be initiated pre-operatively and continued throughout the hospital stay for malignant surgery	Moderate	Low	Strong	Strong
	Prophylaxis should be initiated pre-operatively and continued throughout the hospital stay for benign surgery	Low	Low	Weak	Weak
	Extended postoperative prophylaxis	Low	Low	Weak	Weak
ANTIMICROBIAL PROPHYLAXIS	IV antibiotics should be administered routinely within 60 min before vaginal hysterectomy	n/a	High	n/a	Strong
	Antibiotic prophylaxis may be considered for vaginal surgery without hysterectomy	n/a	Low	n/a	Weak
	Antibiotic prophylaxis may be considered for vulvar surgery	Low	n/a	Strong (Radical vulvectomy)	n/a
STANDARD ANESTHETIC PROTOCOL AND FLUID MANAGEMENT	Use of short acting anesthetics	Low	Low	Strong	Strong

	Objective monitoring of the level of neuromuscular block and ensuring complete reversal	High	High	Strong	Strong
	Fluid balance to achieve euvolemia	Moderate	Moderate	Strong	Strong
	Preemptive analgesia is recommended for vaginal surgery	n/a	Moderate	n/a	Strong
URINARY DRAINAGE	Retrograde bladder fill for voiding trial should be considered for vaginal procedures	n/a	High	n/a	Strong
	Urinary catheters should be removed as soon as possible for vaginal procedures	n/a	High	n/a	Strong
	Urinary catheters should be removed as soon as possible for vulvar procedures	Low	n/a	Strong	n/a
POSTOPERATIVE ANALGESIA	A multimodal post-operative analgesic protocol should be used routinely and home- going opioid prescriptions should be minimized	High	High	Strong	Strong
	Combination of acetaminophen and non- steroidal anti-inflammatory drugs should be used	High	High	Strong	Strong
PREOPERATIVE AND POSTOPERATIVE NUTRITION	Patients should be encouraged to eat a light snack up until 6 h, and clear fluids (including oral carbohydrate drinks) up until 2 h, prior to initiation of anesthesia.	High	High	Strong	Strong
	A regular diet within the first				

	24 hours after vaginal/vulvar surgery is recommended.	Moderate (by indirectness)	Moderate (by indirectness)	Strong	Strong	
POSTOPERATIVE DRESSING CARE	Vaginal packing does not decrease post-operative bleeding and hematoma formation or increase postoperative pain	n/a	High	n/a	Strong	
	If used, vaginal packing should not be left in for more than 24 hours	n/a	Low	n/a	Strong	
	Occlusive dressings may be used post-laser to promote healing	Low	n/a	Weak	n/a	
POSTOPERATIVE DRAINS AND ADJUVANT THERAPIES	Inguinofemoral drains should continue until < 30-50 cc/day of drainage (cancer surgery)	Moderate	n/a	Strong	n/a	
	Saphenous vein preservation should be considered in all Inguinofemoral lymph node dissection (cancer surgery)	Moderate	n/a	Strong	n/a	

## Table 2:

Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system rating of quality and strength of evidence

EVIDENCE QUALITY LEVEL	DEFINITION
HIGH	Subsequent research unlikely to change confidence in estimate of effect
MODERATE	Subsequent research likely to have impact on estimate of effect and may change estimate
LOW	Subsequent research very likely to have impact on estimate of effect and likely to change estimate
VERY LOW	Any estimate is uncertain
RECOMMENDATION	DEFINITION
LEVEL	
STRONG	Desirable effects of intervention clearly outweigh, or clearly do not
	outweigh, the undesirable effects
WEAK	Effects are much more unclear

Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ*. 2008;336(7650):924-926.

AD Altman: Conceptualization, Methodology, Investigation, Writing original draft, Collation of sections, Reviewing and editing final draft; **M Robert**: Investigation, Writing original draft, Reviewing and editing final draft; **R Armbrust**: Investigation, Writing original draft, Reviewing and editing final draft; **WJ Fawcett**: Investigation, Writing original draft, Reviewing and editing final draft; **M Nihira**: Investigation, Writing original draft, Reviewing and editing final draft; **CN** Jones: Investigation, Writing original draft, Reviewing and editing final draft; **CN** Jones: Investigation, Writing original draft, Reviewing and editing final draft; **K Tamussino**: Investigation, Writing original draft, Reviewing and editing final draft; **J Sehouli**: Investigation, Writing original draft, Reviewing and editing final draft; **SC Dowdy**: Methodology, Investigation, Writing original draft, Reviewing and editing final draft, Supervision; **G Nelson**: Methodology, Investigation, Writing original draft, Reviewing and editing final draft, Supervision

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