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Volume-controlled versus short drainage after inguinofemoral lymphadenectomy in vulvar cancer patients: A Dutch nationwide prospective study

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HIGHLIGHTS

- Significantly less lymphocele formation after volume-controlled drainage
- No difference in the incidence of wound breakdown and/or wound infection
- Significantly less patients with ≥1 complication after volume-controlled drainage

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ABSTRACT

Objective. Inguinofemoral lymphadenectomy for patients with vulvar squamous cell carcinoma is associated with a high incidence of postoperative wound complications, which may be influenced by inguinal drain management. The aim of this nationwide prospective study (MAMBO: Morbidity And Measurement of the BOdy) was to assess the feasibility and the incidence of complications after volume-controlled versus short drainage.

Methods. The MAMBO study consisted of two observational studies in all eight oncology centers in the Netherlands, conducted between 2012 and 2016. In the first study, the drain was removed when the production was <30 ml/24 h, except in the first 48 h, and after a maximum of 28 days (MAMBO-IA). In the second study, the drain was removed five days postoperatively regardless of production (MAMBO-IB). We assessed the complications within eight weeks after surgery using logistic regression to compare the incidence of one or more complications between the two drainage protocols, adjusting for possible confounders.

Results. We included 77 patients (139 groins) for volume-controlled drainage and 64 patients (112 groins) for short drainage. Volume-controlled drainage was associated with significant less lymphocele formation. Moreover, we found no difference in wound infection or primary wound breakdown. The estimated incidence of one or more complications was 46% per groin after volume-controlled drainage versus 75% after short drainage, (RD 29% (95% CI 8, 49) $p = 0.006$).

Conclusions. This prospective study shows that volume-controlled drainage is associated with significantly less complications compared to short drainage. We therefore recommend volume-controlled drainage after inguinofemoral lymphadenectomy in patients with vulvar squamous cell carcinoma.

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1. Introduction

Vulvar squamous cell carcinoma (SCC) is a rare disease and accounts for approximately 3–5% of all female genital malignancies [1]. The incidence is approximately 1–2 per 100.000 [2].

The standard treatment for patients with early stage SCC of the vulva consists of wide local excision (WLE) of the tumor combined with a sentinel lymph node (SLN) procedure and/or inguinofemoral lymphadenectomy (IFL). In patients with a primary unifocal vulvar SCC measuring less than four centimeters without suspicious groin lymph nodes; a SLN procedure is indicated and an IFL can be safely omitted [3]. Although the SLN procedure is the preferred treatment in the Dutch guidelines, in around half of the patients an IFL is still indicated based on multifocal tumors, tumors larger than four centimeters, recurrent disease and/or positive SLNs [4].

Unfortunately, IFL has significant short- and long-term complications. The most common short-term complications are wound breakdown, wound infection and formation of lymphoceles and are reported in up to 85% of the patients [5]. Development of lymphedema and cellulitis/erysipelas are the most documented long-term complications.

Efforts have been made to adjust the surgical technique for IFL in order to reduce the associated complications. After the implementation of several new surgical techniques such as triple incisions and sparing of the saphenous vein, the morbidity after IFL decreased, but still remains high and clinically relevant [6–9].

The direct postoperative management for patients with vulvar SCC may reduce the incidence of complications; however, it has not been described extensively and only retrospective studies are published regarding this subject. The usage of prophylactic antibiotics or prophylactic compression stockings did not reduce the postoperative complications [10–12]. Regarding postoperative drain management of the groin in vulvar SCC patients, there is no (inter)national consensus on duration of drainage.

Until now, both volume-controlled and short drainage of the groin are used. Published literature used volume-controlled drainage and removed the drain when the output was <30–50 ml/24 h [6,10,13]. However, the reasons for these specific drain policies were not elaborated and none of the studies compared different drain protocols. Removal of the drain irrespective of the amount of output after several days, may be accompanied by an increase in the incidence of lymphoceles [4]. On the other hand, long drainage may increase the risk for infection, prolonged hospital stay and gives more discomfort for the patient.

Therefore we conducted a nationwide prospective study (MAMBO: Morbidity And Measurement of the BOdy) to start with a volume-controlled drainage protocol to assess the feasibility of such a protocol and to assess the incidence of complications; this was followed by a short drainage protocol to finally compare complication rates of both protocols in order to formulate a standardized national drain protocol.

2. Methods

In this prospective multicenter MAMBO (MAMBO: Morbidity And Measurement of the BOdy) study patients were included from eight oncology centers which are united in the Dutch Gynaecologic Oncology Group (Radboud university medical center Nijmegen, University Medical Centre Groningen, Center for Gynaecologic Oncology Amsterdam, location The Netherlands Cancer Institute/Antoni van Leeuwenhoek hospital and Academic Medical Centre Amsterdam, Leiden University Medical Centre, Erasmus Medical Centre Rotterdam, Maastricht University Medical Centre and Catharina Hospital, Eindhoven). All participating centers are expert centers in the treatment of vulvar cancer.

Patients aged ≥18 years with a primary or recurrent SCC of the vulva with an indication for unilateral or bilateral IFL were eligible to participate in this study. Patients with an indication for a SLN procedure only, were not eligible for this study. Further exclusion criteria were previous radiotherapy on the vulva or groins, previous pelvic lymphadenectomy, histology other than SCC and an indication for IFL with the 'en bloc' approach of the vulva and groins.

Two consecutive protocols were performed to assess the feasibility of the two drainage protocols and to compare the incidence of complications. First, patients were included in the volume-controlled drainage protocol (MAMBO-IA) during a period of 21 months (October 2012–June 2014). Thereafter the treatment protocol was changed and patients were included in the short drainage protocol (MAMBO-IB) (March 2015–December 2016).

There were several reasons why the MAMBO study group has decided not to perform a randomized trial but to choose for two study protocols. First of all, the incidence of vulvar cancer is low. Secondly, there is no standard treatment regimen defined for the duration of drainage. Furthermore, the feasibility of especially the long drainage protocol (patients were discharged from the hospital with drains in situ) was unknown. Both the design and the treatment protocol of both studies were identical except the timing of removal of the drain.

Patients were asked to participate in the MAMBO study during their initial visit at the outpatient clinic. The patient information form was given and all patients had to sign for informed consent for collecting data. The local ethical committees approved both protocols (registration numbers 2012–246 and 2014–1491).

The surgical technique of the IFL consisted of separate incisions parallel to the inguinal ligament. The extent of the dissection was the inguinal ligament cephalad, the adductor longus muscle medially and the sartorius muscle infero-laterally. After opening the cribriform fascia, all nodes bearing fatty tissue medial from the femoral vein was removed as well. No standard ligation of the saphenous vein nor standard sartorius transposition was performed. Thereafter, a high vacuum Redon continuous suction drain was placed in the operated groin. Postoperatively, the drain production was measured daily and the groin wounds and drains were inspected by a physician during hospital stay and/or by a homecare nurse or general practitioner in discharged patients.

For patients in the volume-controlled drainage group, the drain was removed when the production of the drain was <30 ml/24 h (except for the first 48 h after surgery) with a maximum of 28 days. For patients treated by short drainage, the drain was removed on the fifth postoperative day (day of operation is defined as day zero) irrespective of the drain production.

The total follow up time was eight weeks after surgery: two and eight weeks postoperatively all patients were seen routinely at the outpatient clinic for a visit and were examined by a gynecologic oncologist. All short-term complications were assessed and comprised wound infection (purulent exudates and/or positive culture and/or erythema, edema and localized pain), primary wound dehiscence (every spontaneous disrupted groin wound >2 cm) and the occurrence of a lymphocele (collection of lymph fluid in the groin > 5 cm). For a summary of the study protocol see Fig. 1.

2.1. Statistical analysis

Continuous variables were summarized using the median and range, discrete variables were described by frequencies. We performed both intention-to-treat (ITT) and per-protocol (PP) analyses to assess the incidence of complications and the differences between volume-controlled and short drainage. The ITT analysis was the primary analysis.

To estimate the incidence of wound infection, primary wound dehiscence and lymphocele, we used a generalized linear model with a logit link and a binomial distribution. In order to quantify the differences between volume-controlled and short drainage, risk differences were estimated using this model; and for analysis per groin, a random effect was added for patient. In addition, to compare the incidence of ≥1 complication per patient and per groin between both drainage protocols, we adjusted for the following patient and treatment characteristics: diabetes mellitus, active smoker, number of lymph nodes removed, IFL and vulva excision on the same day, closure technique and ligation of the saphenous vein. Statistical analyses were performed using SPSS version 22.0 [14].

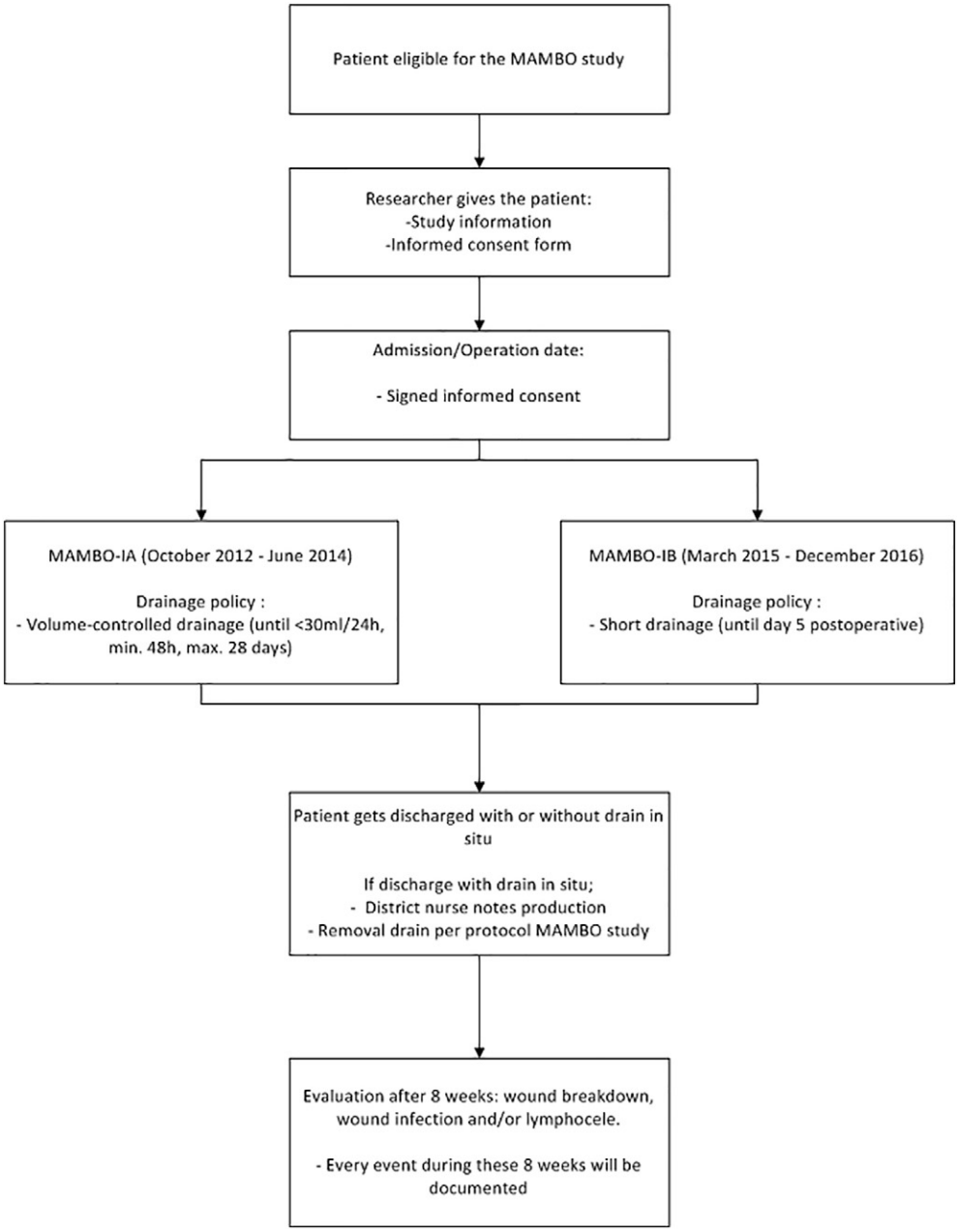

Fig. 1. Summary of the MAMBO study protocol. Abbreviations: IFL = inguinofemoral lymphadenectomy, ml = milliliters, ml/24 h = milliliters per 24 h.

3. Results

We included 141 patients (251 groins); 77 patients (139 groins) for volume-controlled drainage (MAMBO-IA) and 64 patients (112 groins) for short drainage (MAMBO-IB). Table 1 shows that the two groups were similar in terms of patient and treatment characteristics.

Volume-controlled drainage

In Fig. 2 is shown that the median duration of drainage of the groin was 13 days (range 2–40 days) and the median production on the last day of drainage was 25 ml (range 0–720 ml). The duration of hospital stay was median five days (range 1–22 days) and 57/77 (74%) patients went home with at least one drain in situ.

In 79/139 (57%) groins in the volume-controlled drainage group, the drain was removed in deviation of the criteria prescribed in the protocol. In 34/79 (43%) groins, drainage was a shorter period than prescribed (removal before the production of <30 ml/day) and in 39/79 (49%) groins drainage was performed for a longer period (removal after the production was <30 ml/day). In 6/79 (8%) groins, it was unclear when the drain was removed.

Reasons for drainage for a shorter period than prescribed were: in 12 groins wound complications (infection or dehiscence), in five groins drain problems (pain, clotted drain) and in 13 groins drain fell out spontaneously. In groins that were drained for a longer period than prescribed; this was mainly (36/39, 92%) due to logistic difficulties (homecare nurse did not remove the drain, patients waited until their appointment at the outpatient clinic and/or doctors/nurses were not sufficiently familiar with the research protocol).

Short drainage

For groins in the short drainage group, the median duration of drainage was five days (range 3–24 days) with a median production of 60 ml

Table 1
Patient-, tumor-, and operation characteristics of the study population.

	Volume-controlled drainage N = 77 patients, N = 139 groins		Short drainage N = 64 patients, N = 112 groins	
	Median (range)	N (%)	Median (range)	N (%)
Patient characteristics				
Age (years)	68 (35–88)		70 (43–89)	
BMI (kg/m^2)	27.6 (19.4–44.1)		27.6 (18.5–43.0)	
Diabetes mellitus				
- Yes		13 (17)		8 (13)
- No or unknown		64 (83)		56 (87)
Smoking				
- Active		12 (16)		13 (20)
- Not		62 (81)		43 (67)
- unknown		3 (3)		8 (13)
Tumor characteristics				
Diameter tumor (in mm)	30.0 (7–100)		35.0 (2.4–100.0)	
Location tumor				
- Central (≤1 cm from midline)		63 (82)		43 (67)
- Lateral (>1 cm from midline)		13 (17)		18 (28)
- unknown		1 (1)		3 (5)
Invasion depth (in mm)	5.0 (1.5–33)	6.0 (1.0–25.0)		
Focality				
- Unifocal		63 (82)		46 (72)
- Multifocal		13 (17)		17 (27)
- Unknown		1 (1)		1 (2)
LVSI				
- Present		17 (22)		16 (25)
- Absent		57 (74)		44 (69)
- Unknown		3 (2)		4 (6)
Lymph nodes				
Number of nodes removed per groin	8.0 (1−21)		7.0 (0−20)	
Groins with positive nodes		33(25)		35 (32)
Operation				
Type of IFL				
- Bilateral		62 (81)		48 (75)
- Unilateral		15 (19)		16 (25)
Order of procedures				
- Excision vulva and IFL in same procedure		60 (78)		38 (59)
- IFL only		16 (21)		26 (39)
- Unknown		1 (1)		2 (2)
Closure technique per groin				
- Staples		60 (43)		30 (27)
- Stitches		1 (1)		27 (24)
- Intracutanous		42 (30)		46 (41)
- Combination of above or unknown		36 (26)		9 (8)
Variation of the surgical technique per groin				
- Ligation saphenous vein		20 (14)		4 (4)
- Sartorius transposition		2 (1)		0 (0)
Prophylactic antibiotics				
- Yes		74 (96)		63 (98)
- No		1 (1)		0 (0)
- Unknown		2 (3)		1 (2)

Abbreviations: N = total number of patients or groins, BMI = body mass index, IFL = inguinofemoral lymphadenectomy, mm = millimetres, cm = centimeters, LVSI = lymph-vascular space invasion.

(range 0–380 ml) on the last day of drainage, see Fig. 3. The median duration of hospital stay was six days (range 1–26 days) and 10/64 (16%) patients were discharged with at least one drain in situ.

The drain was removed in deviation of the protocol in 13/112 (12%) of the groins. Of these groins, 8/13 (62%) were drained longer and 5/13 (38%) were drained shorter than five days. Reasons for longer drainage were in two groins high drain production on day five, in the other groins the reasons were unknown. Five groins were drained shorter than five days; in two groins the drain fell out spontaneously and in one groin the drain was removed due to pain. For the other two, the reason for early removal was unknown.

3.1. Intention-to-treat analysis

3.1.1. Short-term complications per patient

The estimated incidences of short-term complications after volume-controlled versus short drainage are shown in Table 2. The estimated incidence of a lymphocele was 16% after volume-controlled drainage

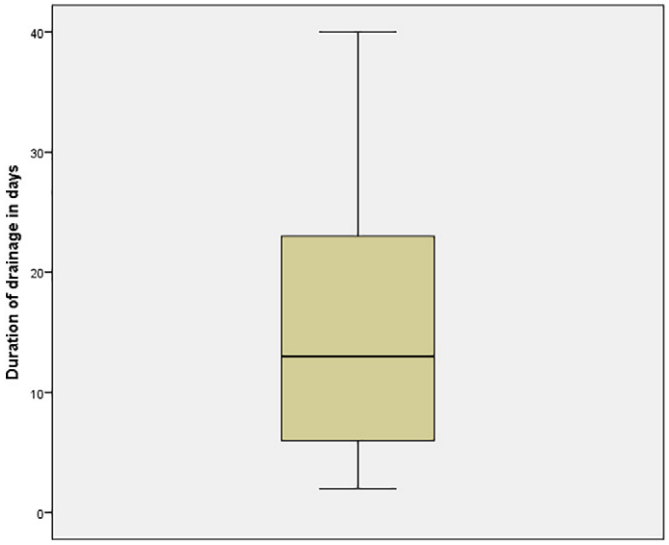

Fig. 2. Duration of drainage in days after volume-controlled drainage.

versus 60% after short drainage (RD 45% (95% CI 30, 59), p < 0.001). The estimated incidence of a wound infection was 52% in both drainage groups and primary wound dehiscence of 8% after volume-controlled drainage versus 11% after short drainage (RD 3% (95% CI −7, 13) p = 0.534). The adjusted incidence of one or more complications (wound infection, primary wound dehiscence or lymphocele) was 67% after volume-controlled drainage versus 91% after short drainage (RD 24% (95% CI 7, 41), p = 0.006).

After volume-controlled drainage, 36/77 (47%) patients with a complication needed treatment such as antibiotics, incision and drainage, wound exposure, necrotectomy, or a combination of these treatments. After short drainage 42/64 (66%) of the patients needed any treatment for a complication. In total 21/77 patients (27%) after volume-controlled drainage needed to be readmitted because of a complication versus 21/64 (33%) after short drainage.

Secondary wound healing, as a result of one of the previous described complications or the treatment given for a complication, was present in 25/77 (32%) patients after volume-controlled drainage versus in 33/64 (52%) after short drainage.

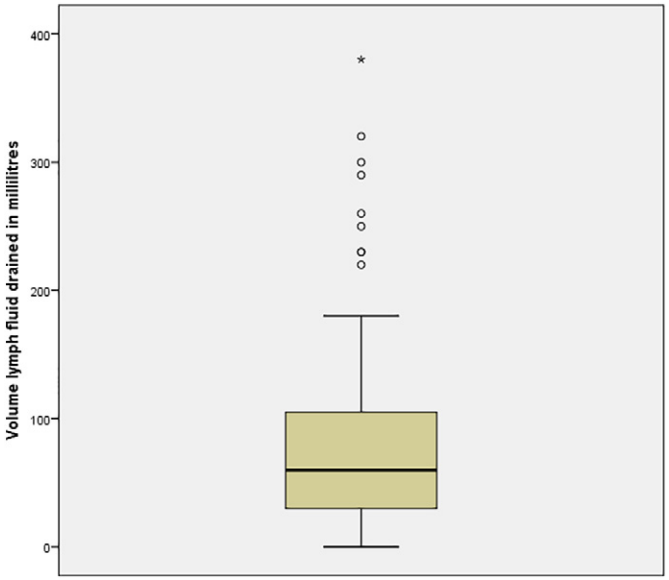

Fig. 3. Volume of drained lymph fluid in milliliters on the last day in situ after short drainage.

3.1.2. Short-term complications per groin

Table 2 shows the estimated incidences of short-term complications per groin after volume-controlled versus short drainage; it shows an estimated incidence of lymphoceles in 10% of the groins after volume-controlled drainage compared to 52% after short drainage (RD 42% (95% CI 31, 52), p < 0.001). The estimated incidence of a wound infection was 40% after volume controlled drainage versus 43% after short drainage (RD 3% (95% CI −9, 15, p = 0.650), the incidence of primary wound dehiscence was estimated in 5% versus 7% of the groins respectively (RD 2% (95% CI −4, 8), p = 0.565).

One or more complications (wound infection, primary wound breakdown or lymphocele) per groin was estimated, after adjustment, in 46% of the groins after volume-controlled drainage versus 75% after short drainage (RD 29% (95% CI 8, 49), p = 0.006).

Secondary wound healing, as a result of one of the previous described complications or the treatment given for a complication, was present and in 42/139 (30%) after volume-controlled drainage versus 52/112 (46%) after short drainage. After 8 weeks of follow up, 110/139 (79%) of the groin wounds were healed in the volume-controlled drainage group versus 68/112 (61%) in the short drainage group.

3.2. Per-protocol analysis

3.2.1. Short-term complications per groin

For groins treated to the study protocol, the estimated incidence of complications is shown in Table 3. The estimated incidence of a lymphocele was 10% after volume-controlled drainage versus 54% after short drainage (RD 44% (95% CI 31, 56), p < 0.001). In addition, the incidence of wound infection (32% versus 45%) and primary wound dehiscence (2% versus 7%) did not significantly differ between the two groups. The adjusted incidence of one or more complications was 30% in the volume-controlled drained groins versus 71% in the short drained groins (RD 41% (95% CI 16, 64), p < 0.001).

3.2.2. Drainage longer or shorter than the study protocol

In Fig. 4 is shown that the incidence of complications differs between groins drained for a longer period or for a shorter period than prescribed by the study protocol.

In the volume-controlled drainage study group, 39/79 (49%) of the groins were drained for a longer period than the protocol described and 34/79 (43%) groins for a shorter period. In the longer drained groins, one or more complications were present in 14/39 (36%) of the groins; in the shorter drained groins 26/34 (76%). However, in these shorter drained groins reasons for early removal was a complication in 12 groins.

In the short drainage study group 8/13 (62%) groins were drained longer than 5 days and 5/13 (38%) were drained shorter. One or more complications were present in 3/8 (38%) of the longer drained groins versus 4/5 (80%) of the shorter drained groins. In none of the groins which were drained shorter than prescribed a complication was the reason for removal.

4. Discussion

Our study is the first prospective study concerning drain management after IFL in vulvar cancer patients. We show that volume-controlled drainage results in a significant reduction of complications compared to short drainage; this difference was mainly related to less lymphoceles. Moreover, the incidence of postoperative wound infections and wound breakdown did not significantly differ between the two groups. Moreover, this study showed that both drainage protocols are feasible; however, the volume-controlled drainage protocol is more difficult to follow. As this study shows the advantages of volume-controlled drainage in terms of a significant reduction of complications, we propose introducing volume-controlled drainage as a standard protocol after IFL.

This study showed that in the volume-controlled treatment group, only 37% of the groins were drained according to the study protocol.

Table 2
Estimated incidence of short-term complications after volume-controlled versus short drainage; intention-to-treat analysis.

	Volume-controlled drainage % (95% CI)	Short drainage % (95% CI)	Risk difference RD (95% CI), p-value
Per patient	N = 77	N = 64	
Wound infection	52% (41, 63)	52% (39, 64)	0% (−17, 16) p = 0.959
Primary wound dehiscence	8% (2, 14)	11% (3, 19)	3% (−7, 13) p = 0.534
Lymphocele	16% (8, 25)	60% (48, 72)	45% (30, 59) p < 0.001
≥1 complication[a]	67% (44, 84)	91% (71, 98)	24% (7, 41) p = 0.006
Per groin	N = 139	N = 112	
Wound infection	40% (32, 48)	43% (34, 52)	3% (−9, 15) p = 0.650
Primary wound dehiscence	5% (1, 9)	7% (2, 12)	2% (−4, 8) p = 0.565
Lymphocele	10% (5, 15)	52% (43, 61)	42% (31, 52) p < 0.001
≥1 complication[a]	46% (9, 88)	75% (24, 97)	29% (8, 49) p = 0.006

Footnote: N = total number of patients or groins.
[a] Including wound infection, wound breakdown, lymphocele, adjustmented for; active smoker, diabetes mellitus, IFL and vulva excision on the same day, number of lymph nodes removed, closure technique, ligation of saphenous vein.

Therefore, we performed both an intention-to-treat and per-protocol analyses. However, the intention-to-treat analysis reflects clinical practice.

As shown in Fig. 4, the incidence of complications differs between groins drained according protocol or for a shorter or for a longer period than prescribed. In the volume-controlled drainage study group, the lowest complication rate (one or more complications) was after drainage according to the protocol (estimated incidence 30%) or for a longer period (14/39, 36%); the highest complication rate was in groins drained for a shorter period than prescribed (26/34, 76%). However, this shorter period of drainage does not fully explain the higher complication rate, as one third of the drains which were removed earlier than the protocol prescribed were removed because of a complication. In conclusion, this study shows that drainage for a longer period, does not seem to harm the patient in terms of complications. However, the longer the duration of drainage, the longer the patient experiences discomfort.

This study was not designed to define an optimal cut-off level for drain production and removal of the drain in which the complication rate is lowest. However, the median production of the drain on the last day in situ after short drainage was 60 ml (see Fig. 3). As short drainage was associated with complications in 91% of the patients, we expect the optimal cut-off level for removal of the drain to be at least below 60 ml.

Not much literature has been published on drainage protocols after IFL in vulvar cancer. In addition to the indication for vulvar cancer patients, IFL is also commonly performed when treating melanoma patients. In these patients, early wound complication rates are reported in 50%–72% of cases [15,16]. As shown in our study and reported in the literature, the complication rate in vulvar cancer patients is much higher than in melanoma patients. This difference can be partly explained by patient characteristics, as patients in our study had a higher median age (10 years) than melanoma patients, and several have reported older age as a statistically significant risk factor for a complication [15, 16]. Additionally, it is likely that the higher the patients age, the greater the presence of co-morbidity. As co-morbidity, such as diabetes, affects the complication rate, this could also explain the difference in complication rates between vulva cancer and melanoma patients.

Besides, lymphadenectomy is also performed in the axilla. In patients treated for breast cancer, the postoperative drain management after axillary lymphadenectomy has been studied in more detail. It covers different aspects of drain management after axillary lymphadenectomy; the need for suction drainage, the amount of negative pressure and the duration of drainage. These studies concluded that suction drainage is mandatory in decreasing lymphocele formation, but that the different amounts of pressure applied is of less value [17–20]. A trend towards decreased lymphocele formation and a decrease in wound healing problems after closed suction drainage was reported [21–24]. Furthermore, several studies and a meta-analysis compared early with late drain removal and concluded that early drain removal was safe, but the incidence of lymphoceles tends to be higher and reported no difference in the incidence of wound infections [25–31].

There are differences in the treatment of axillary lymphoceles and groin lymphoceles. In axillary lymphoceles (repeated) percutaneous drainage is performed. As the anatomy of the groin and axilla differs, the treatment of groin lymphoceles is more complex; this is possible due to more pockets of lymph fluid in the groin. Therefore, it is important to prevent formation of a groin lymphocele. As previously described, both literature on breast cancer and our study showed less lymphocele formation using volume-controlled drainage.

The past decades, new surgical techniques for IFL were implemented. This resulted in a decrease of the incidence of complications. However, even after using the volume-controlled drainage, the incidence of complications still remains considerable. Future research should focus on other factors that may play a role in complications after IFL. Besides postoperative care, modifying the surgical technique might be the key factor to decrease the complication rate.

A novel and promising surgical technique is video endoscopic inguinal lymphadenectomy (VEIL). A study in penile cancer patients compared the open procedure versus VEIL in 30 groins (21 patients) and reported complications (skin related events, lymphatic complications, hematoma) in 20% of the groins that underwent VEIL versus 70% in open procedure groins (p = 0.015). The average number of hospitalization days was reduced from 6.4 days to 24 h after VEIL (p < 0.001) [32]. In

Table 3
Estimated incidence of short-term complications after volume-controlled versus short drainage; per-protocol-analysis.

	Volume-controlled drainage % (95% CI)	Short drainage % (95% CI)	Risk difference RD (95% CI), p-value
Per groin	N = 52	N = 99	
Wound infection	32% (19, 45)	45% (36, 55)	13% (−3, 30) p = 0.104
Primary wound dehiscence	2% (−2, 6)	7% (2, 12)	5% (−1, 11) p = 0.119
Lymphocele	10% (2, 18)	54% (44, 63)	44% (31, 56) p < 0.001
≥1 complication[a]	30% (2–88)	71% (11–98)	41% (16–64) p < 0.001

Footnote: N = total number of patients or groins.
[a] Including wound infection, wound breakdown, lymphocele, adjustmented for; active smoker, diabetes mellitus, IFL and vulva excision on the same day, number of lymph nodes removed, closure technique, ligation of saphenous vein.

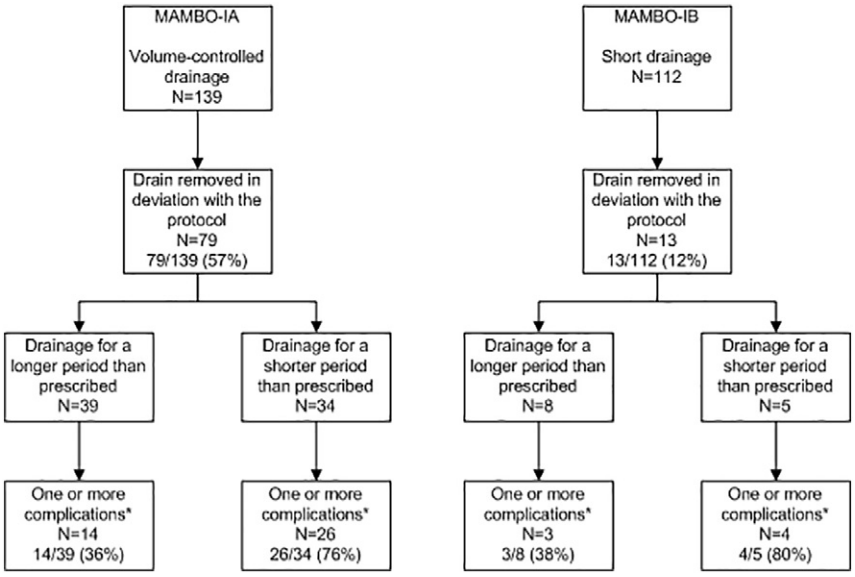

Fig. 4. Incidence of complications per groin displayed by drainage for a longer or shorter period than described by the volume-controlled or short drainage study protocol. Footnote: *including wound infection, wound breakdown, lymphocele.

21 patients with vulvar cancer undergoing VEIL a complication rate (wound necrosis, lymphocele) of only 4.8% is reported [33]. These results show a much lower complication rate compared to our study population. VEIL appears to be a promising technique to decrease the short-term morbidity, although there is a need for more data regarding oncological safety of this method.

In conclusion, this nationwide prospective study showed that mainly due to the reduction in lymphoceles, volume-controlled drainage of the groin after IFL is feasible and is associated with a significant reduction in the incidence of one or more short-term complications compared to short drainage. We therefore propose that volume-controlled drainage after IFL becomes the standard protocol for vulvar cancer patients.

However; the incidence of complications still remains considerable. To further elucidate the emerging and remaining questions future research might focus on surgical techniques and/or other postoperative care protocols to define the optimal care for patients with an indication for IFL in order to further reduce the short-term complication rate.

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