Randomized clinical trial

Randomized clinical trial of platysma muscle suture *versus* no suture for wound closure after thyroid surgery

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Background: **Suturing the platysma muscle during wound closure after thyroid surgery is frequently described in the literature. There is no prospective evidence to support its use or benefit. The aim of this study was to evaluate how a platysma muscle suture influences initial postoperative pain following thyroid surgery.**

Methods: **Patients were assigned randomly to receive a platysma suture or no platysma suture in this prospective, patient-blinded trial. The duration of follow-up was 6 months. The primary endpoint was wound-specific pain 24 h after thyroid resection. Secondary endpoints were intraoperative and perioperative analgesia requirement, postoperative pain and complications until postoperative day 14, and Patient and Observer Scar Assessment Score (POSAS) 6 months after surgery.**

Results: **Forty-one patients were randomized to each group. Visual analogue scale scores for wound-specific pain were lower in patients without a platysma suture 24 h after surgery (mean(s.d.) 3·15(1·46) *versus* 2·17(1·41) in groups with and without suture respectively; $P = 0·002$). There were no differences in the perioperative and postoperative need for analgesics, postoperative wound complications or cervical scar cosmesis 6 months after surgery (mean(s.d.) POSAS 23·99(9·53) *versus* 26·51(8·69); $P = 0·148$).**

Conclusion: **Omitting the platysma muscle suture after thyroid surgery resulted in less wound-specific pain initially, with no difference in postoperative wound complications or cosmetic results. Registration number: NCT02951000 (http://www.clinicaltrials.gov).**

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Introduction

Thyroid surgery is performed widely for benign and malignant thyroid diseases, with over 76 000 patients operated per year in Germany in 2015[1]. Although several prospective randomized studies[2–4] have investigated different skin closure techniques in thyroid surgery, no prospective evidence exists for the clinical benefit of the apparently common practice of suturing the platysma muscle. The platysma is a subcutaneous sheet of muscle originating from the superior portions of the pectoralis major and deltoid muscles, and inserting on the inferior mandible[5]. Functionally, it depresses the corners of the mouth. Approximating the platysma muscle is thought to minimize wound space, and to potentially reduce seroma formation and wound complications. On the other hand, the inserted suture material can cause a foreign body reaction with granuloma formation that might have a negative impact on the cosmetic result and postoperative pain[6].

The aim of this RCT was to evaluate how a platysma muscle suture affects initial postoperative pain and scar cosmesis following thyroid surgery.

Methods

All patients scheduled for primary thyroid surgery were considered eligible and screened for inclusion in this trial at the outpatient clinic of the University Hospital of Tuebingen, between May 2016 and November 2016. Exclusion criteria were: known wound-healing disorders, diabetes mellitus, known malignant disease before operation, previous neck surgery, coagulopathy, intolerance or contraindication to the medications used in the trial, and inability to understand the protocol and patient information leaflet. Informed written consent was obtained from each patient. The study was conducted in accordance with the Helsinki Declaration and was approved by the local ethics review board of Tuebingen University. The

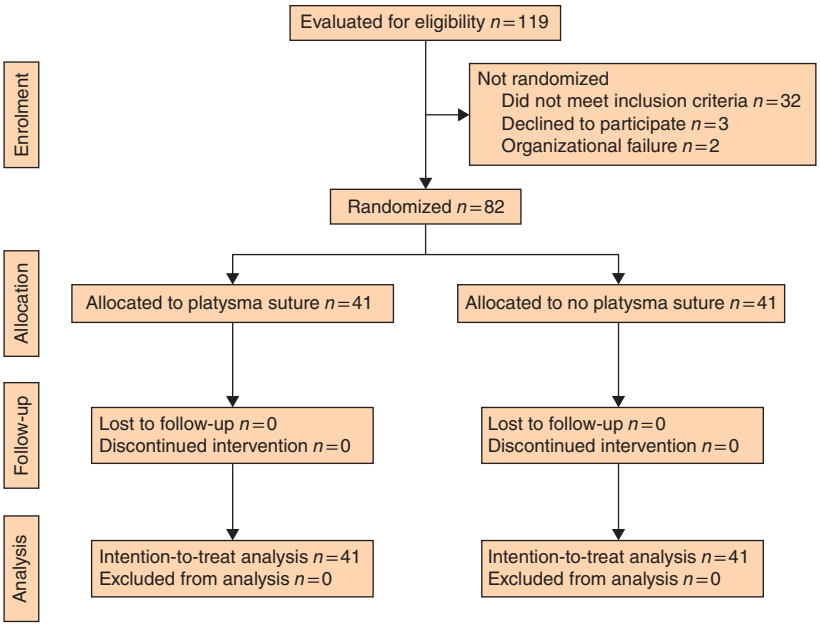

Fig. 1 CONSORT flow diagram for the trial

CONSORT recommendations[7] for reporting randomized trials were followed. The study was registered in a clinical trial registry (www.clinicaltrials.gov; NCT02951000).

General anaesthesia protocol

General anaesthesia was induced with intravenous propofol (2–3 mg/kg) and supplemented with sufentanil (0·3 μg/kg). Orotracheal intubation was facilitated by the administration of rocuronium (0·5 mg/kg), and anaesthesia was maintained with 0·7–1·0 minimum alveolar concentration of sevoflurane. Further boluses of sufentanil (0·1–0·2 μg/kg) were administered when appropriate. The total amount of intraoperative sufentanil administered was recorded.

Postoperative pain management protocol

Piritramide (2·5 mg intravenously) was given repeatedly in the recovery room if pain registered 5 or more points on a visual analogue scale (VAS). The standard postoperative pain management protocol included paracetamol (1 g orally or intravenously 4 times per day) for 7 days and rescue opioids (50–100 mg tramadol) if pain registered 5 or more points on the VAS. Every dose of drug administered until day 14 after surgery was registered.

Randomization

A randomization plan was generated using online software (http://www.graphpad.com/quickcalcs/index.cfm). Block randomization in groups of ten patients was used to ensure a balance in group numbers throughout the trial. Patients were randomized to receive either a platysma suture or no platysma suture at wound closure. Patients were unaware of their allocated group.

Surgical technique

All operations were performed according to a standard protocol. Briefly, the patient was positioned supine with the torso elevated 30° and no neck extension. An incision was made between the glottis and suprasternal notch in the middle of the neck according to the estimated thyroid gland size. After horizontal incision of the platysma with monopolar electrocautery, the subplatysmal space was developed upwards to the cricoid and down to the upper sternal notch. The thyroid compartment was accessed between the sternohyoid muscles. After completion of thyroid removal (either hemithyroidectomy or total thyroidectomy), haemostasis was performed with bipolar electrocauterization and/or titanium clips. For wound closure the sternohyoid muscles were apposed with polyfilament polyglactin 910 thread (Vicryl® 3/0; Ethicon, Norderstedt, Germany). In the group randomized to

receive a platysma suture, a running suture of polyfilament polyglactin 910 was used. This was omitted in the other group. Finally, the skin was closed in all patients with a running absorbable intracutaneous monofilament suture (Monocryl® 4/0; Ethicon). The wound was covered with a sterile wound dressing for 48 h. No wound drains were used.

Outcome measures and data collection

The primary outcome measure was wound-specific postoperative pain 24 h after surgery, assessed on a VAS, ranging from 0 (no pain) to 10 (worst possible pain)[8]. Secondary outcome measures included VAS pain scores 6 h after surgery and on days 2 and 14, duration of surgery and postoperative analgesia consumption. Wound seroma or haematoma was diagnosed based on the presence of visible swelling when the head was reclined and/or the clinical sensation of local pressure after operation. In the latter instance, an additional ultrasound examination was performed to verify whether a fluid collection/haematoma was present. Postoperative wound infection was defined as any local erythema requiring antibiotics, or wound dehiscence with secretion of putrid or foul-smelling fluid. Disorders of the functional anatomy of the neck were defined as new-onset clinically described swallowing problems and reduced depression of the corners of the mouth 6 months after surgery.

Cosmesis of the cervical scar was registered 6 months after thyroidectomy using a validated tool (Patient and Observer Scar Assessment Score, POSAS)[9]. Background variables such as ASA fitness grade, BMI, duration of operation, type of surgery (hemithyroidectomy or total thyroidectomy), intraoperative skin incision length, thyroid specimen weight, diagnosis (benign, Graves' disease, malignant) and duration of hospital stay were assessed.

Statistical analysis

The sample size was calculated based on the detection of a minimum difference of 1 unit on the ten-point VAS between groups for the primary endpoint (pain score at 24 h). To achieve 90 per cent power with two-sided P less than 0·050 regarded as significant, 41 patients per group were required. Analysis was performed on an intention-to-treat basis with all patients remaining in the group to which they were allocated. Data were entered into a computerized trial database and analysed using the statistical software SPSS® (IBM, Armonk, New York, USA). The Mann–Whitney U test was used to compare continuous variables, and the χ^2 test or Fisher's exact test for analysis of discrete variables.

Table 1 Patient and surgical characteristics

	Platysma suture ($n = 41$)	No platysma suture ($n = 41$)	P‡
Age (years)*	52 (21–74)	50 (22–77)	–
Sex ratio (F : M)	34 : 7	33 : 8	–
BMI (kg/m^2)†	29·1(5·9)	27·2(6·2)	–
ASA fitness grade			
I	7	11	
II	32	30	
III	2	0	
Specimen weight (g)†	49·0(35·5)	54·0(56·2)	0·513
Duration of surgery (min)†	77·8(29·8)	64·9(20·6)	0·042
Type of surgery			1·000§
Total thyroidectomy	27	27	
Hemithyroidectomy	14	14	
Incision length (cm)†	6·1(1·3)	6·1(0·8)	0·619
Diagnosis			0·553§
Benign nodules	34	30	
Graves' disease	6	9	
Malignant disease	1	2	

Values are *median (range) and †mean(s.d.). ‡Mann–Whitney U test, except §χ^2 test.

Results

A total of 119 patients were screened for eligibility; 82 of these fulfilled the inclusion criteria and were assigned randomly to the two study groups (*Fig. 1*). Patient characteristics and surgical details are shown in *Table 1*. The distribution of patients between the groups was well balanced.

The primary endpoint, pain score 24 h after surgery, was lower in patients without than in those with a platysma suture (mean(s.d.) VAS score 2·17(1·41) *versus* 3·15(1·46) respectively; $P = 0·002$). Pain scores 6 h after surgery were also significantly lower in the group with no platysma suture (2·24(1·51) *versus* 3·17(2·05); $P = 0·025$). There were no significant differences at other time points (*Table 2*).

Duration of surgery was shorter for the group without a platysma suture (mean(s.d.) 64·9(20·6) *versus* 77·8(29·8) min; $P = 0·042$). This was, however, not solely due to omission of the platysma suture, as the difference was largely accounted for by three patients who had an especially long procedure. These patients, who were all in the platysma suture group, had operating times of 184 min (technical problems with nerve monitoring), 179 min and 156 min (prolonged dissection in Graves' disease). The duration of operation in other patients in both groups ranged from 40 to 120 min.

Need for perioperative and postoperative analgesics, and the cosmetic appearance of the cervical scar 6 months after surgery did not differ between the two groups (*Table 2*). Wound-specific complications occurred in five patients (4 uncomplicated wound infections treated with oral

Table 2 Outcome measures

	Platysma suture ($n = 41$)	No platysma suture ($n = 41$)	P‡
VAS score*			
Before surgery	0·24(0·86)	0·2(0·95)	0·466
6 h	3·17(2·05)	2·24(1·51)	0·025
24 h	3·15(1·46)	2·17(1·41)	0·002
Day 2	1·82(1·46)	1·54(1·31)	0·294
Day 14	0·39(1·05)	0·42(1·05)	0·853
Intraoperative opioids (μg sufentanil)*	60·49(14·27)	55·18(11·99)	0·101
Opioids in recovery room (mg piritramide)*	9·23(4·20)	8·97(5·16)	0·868
Need for postoperative rescue opioids	3	2	1·000§
Wound-specific complication			0·513§
Seroma/haematoma	1	0	
Wound infection	2	2	
Length of hospital stay (days)†	2 (2–3)	2 (2–2)	0·320
Scar assessment*			
POSAS	23·99(9·53)	26·51(8·69)	0·148
PSAS	11·44(4·71)	13·30(5·15)	0·096
OSAS	12·95(5·65)	13·22(5·58)	0·963
Scar length after 6 months (cm)*	5·64(1·05)	5·42(0·87)	0·370

Values are *mean(s.d.) and †median (range). VAS, visual analogue scale; POSAS, Patient and Objective Scar Assessment Score (11–110 points); PSAS, Patient Scar Assessment Score (6–60 points); OSAS, Objective Scar Assessment Score (5–50 points). ‡Mann–Whitney U test, except §χ^2 test.

antibiotics only, and 1 ultrasound-proven local seroma not requiring any further treatment). No clinically relevant disorder of the functional anatomy of the neck was noted after 6 months.

Discussion

Suturing the platysma muscle during wound closure after cervicotomy seems to be common practice in many countries throughout Europe, as it has been described in many larger trials[2–4,10–12]. There is no prospective evidence, however, to support this practice, nor any evaluation of its clinical benefit. The results of this RCT indicate that suturing the platysma muscle during wound closure following thyroid surgery can be omitted. Significantly less wound-specific pain was observed in the initial postoperative period, with equivalent long-term cosmetic results of the cervical scar and no difference in postoperative wound complications.

Muscle fibres of the platysma merge in the midline, with possible dehiscence in the lower cervical region, which can be misinterpreted as a missing platysma in very short cervicotomies[13]. Of special interest when evaluating the usefulness of a platysma muscle suture is whether reconstruction of the platysma muscle has an impact on function, postoperative pain, cosmesis or postoperative seroma formation in the wound.

It was reported by de Almeida and colleagues[14] that the cranial portions of the platysma muscle mainly seem to play a role in the functional anatomy of the mouth. Consequently, it can be assumed that a more caudal incision of the platysma muscle, as for thyroid resection, has little impact on depression of the corners of the mouth. In the present trial, no functional limitation of mouth mimic was observed after 6 months.

Postoperative pain after thyroid surgery is normally moderate and limited to the first few days, usually necessitating pain medication with non-opioid analgesics[15]. Some patients need rescue medication with opioids in this early period, which potentially delays hospital discharge[11]. In the present trial, reduced pain scores were registered the early postoperative period in the group with no platysma suture, whereas no significant differences between groups were observed after 48 h. The higher pain scores in the sutured group might be explained by local oedema and compromised blood circulation caused by the platysma muscle suture. Polyfilament absorbable sutures such as polyglactin 910 have been shown to cause an inflammatory tissue reaction and oedema, which can influence the development of postoperative pain[6,16]. Furthermore, an RCT[17] comparing skin closure only *versus* two-layered subcutaneous plus skin closure, after removal of the great saphenous vein during coronary artery bypass surgery, showed greater initial postoperative pain and local numbness when subcutaneous sutures were used.

Another aspect of importance after thyroid surgery, especially from the patient perspective, is the cosmetic appearance of the cervical scar[18]. Using the validated POSAS tool[9], no difference in cervical scar cosmesis was found in

the present trial, either from the patient or observer perspective. In addition, no difference in scar width or keloid formation was observed between the two groups. A limitation of the present trial is that it was not sufficiently powered to detect minor differences in POSAS score. Therefore, the possibility of a type II error cannot be completely ruled out. Although the observer-related part of the score (Objective Scar Assessment Score) was almost identical in the two groups, there was a slight but non-significant difference in the patient-reported outcome (Patient Scar Assessment Score). It is, however, unlikely that such a slight difference would be of clinical relevance.

No differences in clinically relevant seroma/haematoma formation or wound infection were observed between the two groups. Owing to the relatively small numbers of patients and the low incidence of seroma formation in both groups, no definitive statements can be made regarding this issue.

Neither BMI nor thyroid specimen weight had any impact on the findings in this trial. Although the duration of operation was significantly shorter in the group without a platysma suture, this was largely explained by especially long operating times in three patients in the platysma suture group. However, these three patients were not responsible for any differences in the primary endpoint or cosmesis after 6 months.

Disclosure

The authors declare no conflict of interest.

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