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ORIGINAL ARTICLE

A comparison of aesthetic outcome between tissue adhesive and subcuticular suture in thyroidectomy wound closure in a multiracial country: A randomized controlled trial

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Summary *Objectives:* Monofilament sutures, both absorbable and non-absorbable, have been used for wound closure. Tissue adhesive has been used in closure of clean, low tension wounds. However, there have been very few published studies on the aesthetic outcomes in neck surgeries. The aim of this study is to compare the patients' and doctors' satisfaction scores in the aesthetic outcome between both methods of closure of thyroidectomy wounds using validated scoring systems.
Methods: A double-blinded randomised controlled trial comparing the aesthetic outcome between tissue adhesive and conventional suture was conducted among patients undergoing thyroid and parathyroid surgeries. Ninety-six patients were randomised into two treatment groups. Patients' wounds were scored by an independent observer using the SBSES score at 6 weeks postoperatively and observer component of the POSAS score at 3 months.
Results: Forty-nine patients were randomised to the tissue adhesive group while forty-seven patients received the conventional method. There was no statistical difference in the aesthetic outcome using the patient's scoring system between both arms, with a median score of 9 ($p = 0.25$, SD $\pm$ 6.5). The observer's satisfaction score using POSAS was also not statistically significant (median score of 14 ($p = 0.77$, SD $\pm$ 6.2)). No significance was found in the observer's median score using the SBSES scoring system either (score 3, $p = 0.12$,

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SD ± 1.3). However, there was significant reduction in the duration of closure using glue (4.42 mins vs 6.36 mins, $p < 0.05$).
Conclusion: Tissue adhesive offers a comparable cosmetic result to the absorbable suture in thyroidectomy wound closure.

1. Introduction

Thyroidectomy is a common general surgical operation performed via a collar neck incision. The cosmesis and neck mobility have been of concern for the patients, mainly among females. Various techniques have been used to improve the aesthetic outcome of the scar.[11] For the last decade, remote access thyroidectomy and natural orifice transluminal endoscopic surgery (NOTES) have been popularised, as they leave no visible scar on the neck and therefore are deemed to yield superior cosmetic result.[14] However conventional thyroidectomy is still the mainstay of treatment for most of the thyroid diseases, particularly thyroid cancer.

Customarily monofilament sutures, either absorbable or non-absorbable, have been used for the wound closure. However different methods of skin closure like tissue adhesive glue are also commonly used among surgeons.[20] Octyl-2-cyanoacrylate is a tissue adhesive that has been used in many types of surgery, including breast and paediatric surgeries, for closure of skin incisions and lacerations with minimal or no tension, as well as wounds affecting the joints where flexion is of importance.[15–18] Leukosan® Adhesive is a synergy of both octyl-2-cyanoacrylate and n-2-butylcyanoacrylate which has been used widely in hospitals around Malaysia for closure of low tension wounds.

Only one recent study in Italy had been carried out on the assessment of the quality of the scar after total thyroidectomy comparing octylcyanoacrylate and subcuticular absorbable suture.[1] To date, there has been no local study available comparing the cosmetic results of thyroidectomy wound using synthetic glue or conventional suture, particularly in a multi-racial country with hot and humid equatorial climate.[19]

This study had been carried out to compare both methods in the repair of low tension and clean incisions in post thyroidectomy patients in the context of the aesthetic outcome in Malaysia, a country with multiple ethnic groups and equatorial weather. It compared the cosmesis of the wound from both the patient's and doctor's perspectives 3-months postoperatively. This study also looked into the doctor's assessment 6 weeks after the surgery as well as the presence of wound dehiscence a week postoperatively.

2. Materials and methods

This was a single-centred, double-blinded randomised controlled trial looking into patients who underwent total thyroidectomy, hemithyroidectomy or parathyroidectomy in Penang General Hospital from January 2014 to March 2015. All surgeries were performed by the same group of breast and endocrine surgeons. Inclusion criteria were any patients aged 18 years and above who underwent the above mentioned surgeries. Patients who had previous neck incision over the site of intended incision, history of allergy to the skin adhesive, cervical lymphadenopathy needing radical neck dissection, presence of any dermatological conditions, poorly controlled medical conditions and immunocompromised or immunosuppressed patients or those who were unable to provide informed consent were excluded from the recruitment.

From the given study period, a total of 96 patients were recruited from the General or Endocrine Surgical clinics, with a minimum of 45 patients on each arm required. Patients were blinded to the mode of closure based on the random selection of envelopes containing the methods of closure by the patients.

Standard intraoperative techniques were applied with closure of the platysmal flap using absorbable suture to minimise skin tension. Subcuticular method of closure using braided polyglycolic acid 4/0 suture was used for the control group, while tissue adhesive glue was applied for the trial group. Both methods of closure were performed by either one of the two consultant breast and endocrine surgeons in Penang General Hospital. First application of the glue took around 10–15 s to dry up, as recommended by the manufacturer. All wounds were dressed with OpSite dressing and postoperative advice was given to patients before discharge.

2.1. Sample size calculation

We planned for a study of continuous response variable from the independent control group (subcuticular suture) and experimental group (adhesive). Based on a study by Nipshagen MD, et al[2] on the comparison between skin adhesive and sutures in reduction mammoplasty, we used a difference in between groups (delta 0.6) with standard deviation of 1.0 and came out with a sample size of 45 patients in each arm with a power of 0.8 and alpha of 0.05. A dropout rate of 55% was included along the study period due to heavy volume of patients who were lost on follow up.

2.2. Randomisation

Block randomisation using sealed and numbered envelopes was applied using an online randomisation application 'Sealed Envelope'. The envelopes were randomly selected by the patients during admission, and were brought into the

operation theatre and revealed only upon the commencement of skin closure.

This was a double-blinded study involving the patients and an independent observer. Patients and the medical officer who were assigned to assess the wound were blinded to the intervention. The surgeons were also not informed of the method of closure until the envelopes were opened upon commencement of wound closure.

2.3. Data collection

Initial wound inspection and early assessment were done by the endocrine surgeons on day seven postoperatively as a standard postoperative follow-up. Subsequent assessments regarding the cosmetic outcome were done by the appointed senior medical officer.

Patients were followed up six weeks after surgery for first assessment in the surgical outpatient clinic. Stony Brook Scar Evaluation Score (SBSES) was used to measure short-term cosmetic outcome of the wounds.[3,4] The second assessment was done three months later using The Patient and Observer Scar Assessment Score (POSAS), as it is the only scale that considers subjective symptoms of pain and pruritus.[4]

2.4. Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics version 22.0 and all continuous variables were analysed for normal distribution using Kolmogorov–Smirnov test and Pearson's chi square test was used to test for discrete variables. All the variables were noted to be skewed and not normally distributed (KS test < 0.05), thus a non-parametric test (Mann–Whitney U test) was used to test the significance of the independent variables. Wilcoxon signed-rank test was used to look for any significant differences in the various scar parameters between the two treatment arms. The duration of closure was analysed after missing data was imputed using multiple imputation in SPSS. A p value of <0.05 was considered as statistically significant.

3. Results

A total of 192 patients underwent total thyroidectomies, hemithyroidectomies and parathyroidectomies from January 2014 to March 2015. 52 patients were excluded based on the exclusion criteria as well as those who did not consent to participate in the study (Fig. 1). Thus, 140 patients were randomised into two treatment arms. Twenty-three patients were unable to be recruited within the given study time frame. Fifty-seven patients were allocated into Group A (tissue adhesive) with 60 patients into Group B (suture). After exclusion, there were 49 patients in Group A and 47 patients in Group B.

There was no statistically significant difference among the different races in Malaysia between the two arms ($p = 0.38$). There was also no difference between the age groups ($p = 0.57$). The median age of the recruited patients was 52 years old (Table 1). The length of surgical incision showed no statistical significance as well ($p = 0.10$). The median length of the incision measured 6.2 cm ($p = 0.10$, SD $\pm$ 2.2) (Table 1). The surgical technique was standardized as it was done by either one of the two consultant breast and endocrine surgeons. However, there was significant difference in the gender ($p = 0.05$). This was expected as the prevalence of thyroid disorder was higher in women, with the female to male ratio of at least 4:1.[21]

The total patients' satisfaction score 3 months post-operatively using the patient's component of the POSAS score was noted to be not statistically significant, with a median score of 9 (interquartile range from 6 to 34) and a p value of 0.246 (SD $\pm$ 6.5). There were no difference in the rank score between the two arms (sum rank score: glue = 2219.50, suture = 2436.50; $p = 0.25$) (Table 2). There was also no statistical significance in all the other components, with a median score of 1, except for the colour of the scar (median = 3, $p = 0.75$).

The observer's satisfaction component from the POSAS score was also noted to be not statistically significant with a median score of 14 (IQR 5–34) and a p value of 0.772 (SD $\pm$ 6.2). The rank score between both arms showed no significant difference with a rank sum of 2337.00 (glue) and 2319.00 (suture) and a p value = 0.77. There were no differences noted among the components scored from both arms, as well as the sum rank scores.

Similarly, there was no observed statistical difference using the SBSES score, with a median score of 3 ($p = 0.12$, SD $\pm$ 1.3). The sum rank scores were 2170.00 and 2486.00, for glue and suture arm respectively ($p = 0.12$). Most of the wounds were darker than the normal skin (63.5%, $p = 0.22$). It was also shown that 51% of the observed scars had mixed pigmentation (Table 3). There were no incidences of wound dehiscence or infection in the groups observed and no delay in the time of the closure. There were also no cases of hypersensitivity reported in this study.

In view of missing data in the calculation of the duration of closure, after the data was imputed, it was noted that the pooled mean duration of closure for tissue adhesive was 37.84 min as compared to 57.16 min in the counterpart group ($p < 0.05$), with a mean closure time of 4.42 min and 6.36 min respectively. Five patients (5.2%) reported limitations in their daily activities. Three of them complained of daily pain over their wounds, one had stiffness during neck extension while the last one had pain and pruritus (median scores ranging from 9 to 29).

4. Discussion

The perspective of beauty is very subjective. Body image and operation scar are closely related to quality of life. A study done by Bokor et al in Germany showed that thyroidectomy scar did not affect body image in their population.[13] On the other hand, the Koreans think that a noticeable cervical scar will negatively affect their self-body image, and hence quality of life.[12] In our study, we addressed this issue in our population that consists of the Malay, Chinese, Indian and "bumiputra" races. There was no statistical difference in the aesthetic outcome among the different ethnic groups, from both the patient's and the independent observer's perspective.

The observer noticed that those patients with higher score of hyperpigmentation (POSAS score>5) were from the

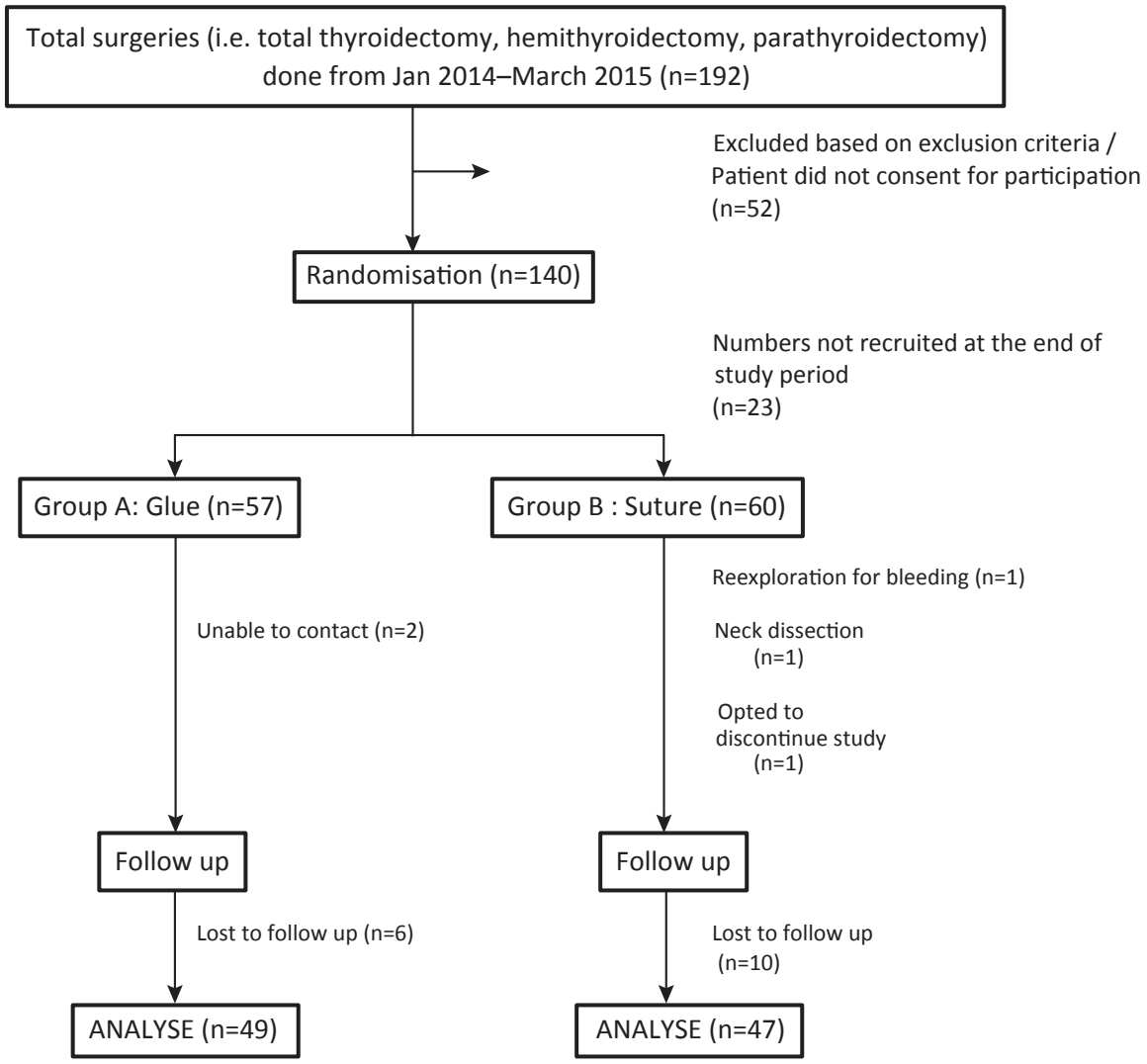

Figure 1 Flowchart of the randomisation of study samples.

Malay (29 out of 43) and Indian ethnicity (9 out of 11). This is due to their higher melanin levels genetically, as noted in a study by Rawlings.[8] On the other hand, the Chinese have approximately half the level of melanin compared to other races with darker pigmentation, like the Indians. We encountered two patients, one Iban in whom was labelled as "bumiputra" and one Vietnamese, with less melanin levels compared to the Malay, but not to the Chinese ethnic group. These two patients were grouped into a separate category for statistical analysis. Similarly, the Malay and the Indonesian were grouped into the same category as they had the almost similar skin complexion. Pigmentation of the wound is rather common in tropical climate like Malaysia due to frequent exposure of the neck to the sunlight. There was discrepancy in the scoring of the pigmentation level by the observer in comparison to the patients themselves in our study, with lower scores noted among the patients. However, the difference was insignificant and the assessment was subjective. Similar result was noted when using the SBSES scoring for the outcome six weeks post operatively, in which the total median score shows no statistical significance (score of 3, ranging from lowest score of 0 and highest score of 5; $p = 0.12$, SD $\pm$ 1.3). The observer scored 84% of the cases as having good appearance. This assessment, however, has a disadvantage of being a subjective tool.

A study that looked into the cosmetic outcome in the early, three-month and one-year post-operative stages showed no difference in the traumatic laceration wound cosmesis after one year of repair using either tissue adhesive or suture.[5] Thus, an assessment at three months' post-operation is sufficient to provide a good measure of long-term cosmetic outcome. In this study, the patient's component of the POSAS score was used to evaluate the cosmetic satisfaction among the subjects three months after surgery. POSAS score provides a good measure in assessing patients' own satisfaction scale based on the symptoms patients experienced.

There was no statistical significant difference in the VAS cosmesis scores in head and neck incisions ($p = 0.44$).[6] However, in a meta-analysis by Tao, et al[7] of randomised controlled trials looking into the early cosmetic outcomes using either skin adhesives or sutures showed that the VAS result between the two methods was significantly different with no heterogeneity in the studies ($Z = 2.19$, $p = 0.03$). In our study, neither method used in the closure exhibited

Table 1 Demographics characteristics of the samples according to the methods of closure.

Characteristics	Glue (%) (n = 49)	Suture (%) (n = 47)	p value (median±SD)
Age (years)			
21–30	6 (12.2%)	4 (8.5%)	0.569 (52 ± 13.8)
31–40	11 (22.5%)	7 (14.9%)	
41–50	6 (12.2%)	11 (23.4%)	
51–60	12 (24.5%)	10 (21.3%)	
>60	14 (28.6%)	15 (31.9%)	
Gender			
Male	17 (34.7%)	8 (17.0%)	0.049
Female	32 (65.3%)	39 (83.0%)	
Race			
Malay/Indonesian	23 (46.9%)	20 (42.5%)	0.378
Chinese	19 (38.8%)	21 (44.7%)	
Indian	7 (14.3%)	4 (8.5%)	
Others[b]	0 (0.0%)	2 (4.3%)	
Surgery			
Total thyroidectomy	18 (36.7%)	30 (63.8%)	0.025
Hemithyroidectomy	10 (20.4%)	7 (14.9%)	
Parathyroidectomy	21 (42.9%)	10 (21.3%)	
Length			
<5 cm	1 (2.1%)	3 (6.4%)[a]	0.096 (6.2 ± 2.2)
5–10 cm	47 (95.8%)	37 (78.7%)[a]	
>10 cm	1 (2.1%)	5 (10.6%)[a]	

[a] Missing data not included in calculation; $p < 0.05$.
[b] This group consists of two patients: a native "Iban" labelled as bumiputra and a Vietnamese.

Table 2 The ranks of total scores in both components in POSAS; $p < 0.05$.

POSAS	METHODS	N	Mean Rank	Sum of Ranks	p value
Patient's component	Glue	49	45.30	2219.50	0.246
	Suture	47	51.84	2436.50	
	Total	96			
Observer's component	Glue	49	47.69	2337.00	0.772
	Suture	47	49.34	2319.00	
	Total	96			

Table 3 SBSES score; $p < 0.05$.

		Number (n = 96)	Percentage (%)	p value
Width	>2 mm	30	31.3	0.891
	≤2 mm	66	68.8	
Height	Elevated/depressed	43	44.8	0.399
	Flat	53	55.2	
Colour	Darker	61	63.5	0.224
	Same/Lighter	35	36.5	
Hatchmarks	Present	20	20.8	0.160
	Absent	76	79.2	
Appearance	Poor	12	12.5	0.076
	Good	84	87.5	

any superiority above the other in term of satisfaction score three months postoperatively.

In a single blinded randomised controlled trial comparing the quality of scar after total thyroidectomy between octylcyanoacrylate and subcuticular absorbable suture, the researchers concluded that better aesthetic outcome was reported by the observer using POSAS scoring system in the suture group with small cervical incisions in the early phase after thyroid surgery ($p = 0.04$). However, there was no significant difference in the patient's self-

assessment score. In our study, we were unable to detect any significant difference in the observer's score, with a median score of 14 ($p = 0.77$, SD $\pm$ 6.2).

A meta-analysis of the randomised controlled trials on octylcyanoacrylate tissue adhesive[9] demonstrated that glue shortened closure time while offering comparable cosmetic results after one year. From our imputed data, we notice a significantly shorter time in closure of the wound using tissue adhesive as well, with a mean difference of 1.94 min ($p < 0.05$). However, this difference in the time saved does not contribute to any significant benefit clinically.

Majority of the patients in the tissue adhesive group were satisfied with the outcome of their scars and this showed that the usage of tissue adhesive may be an option in the closure of neck incisions. It is comparable with the conventional suture method, with only a marginal cost difference but a faster closure time. Chow, et al[10] reported that in 8 out of 12 studies, patients were more satisfied with the use of tissue glue. Thus, tissue adhesive still remains as an alternative for surgeons who prefer to use this method or as per request by patient themselves. Cumulative cost in purchasing the tissue adhesive might not be economical however if there was no difference noted in the outcome of the wound compared to the conventional method of closure.

Nipshagen, et al[2] reported significantly less itching and scar thickness on the breast post-reduction mammoplasty at 6 months after surgery with tissue adhesive ($p < 0.01$). Our study revealed no significant difference in the outcome of pruritus and thickness of the scar post-neck incisions ($p = 0.62$ and 0.33). As there was no wound dehiscence noted from our study, it is safe to surmise that patients with well-controlled underlying disease prior to surgery can use either methods of closure, as preferred by the surgeons or patient themselves.

We found no statistical significance in the degree of pain experienced by the patients based on their own scoring in both groups. Some of the common complaints from patients included the degree of neck stiffness after the conventional suture method. However, in our study, we were unable to detect any difference in the degree of neck stiffness when using tissue adhesive compared to suture. The majority of patients did not have any limitations in their daily activities.

5. Limitations

Future studies including a randomised controlled trial using more objective assessment tools should be carried out before a concrete conclusion can be made regarding the final aesthetic outcome of the wound using either tissue adhesive or the conventional suture method. However, it is still best to apply a subjective assessment tool in assessing the satisfaction level among the patients. A larger scale study including several institutions applying the same study design may produce a better outcome as well.

6. Conclusion

Tissue adhesive offers a comparable result to conventional absorbable suture in the final cosmetic outcome of thyroidectomy wounds based on the patients' feedback, regardless of the ethnicity of the population. However, a multi-institutional randomised controlled trial with application of several objective scar assessment tools will be helpful in the future before guidelines can be drawn up.

Conflict of interest

The author declared no conflict of interest and this is a non-profit and non-funded study. Author has no affiliation with the manufacturer of Leukosan® Adhesive.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.asjsur.2018.09.014.

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