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Original Article

Efficacy of surgicel™ for hemostasis following thyroid surgery: a prospective clinical study

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Abstract: Objective: Complications such as bleeding and hematoma can be seen in an early period following thyroidectomy operations, and hematoma may be lethal in some rare cases if not intervened. In this study, we investigated the efficacy of oxidized cellulose (Surgicel™) in hemostasis after thyroidectomy operation. Materials and methods: A prospective study is designed including 80 patients that underwent total thyroidectomy operation. The study group consisted of patients that had Surgicel placed at the operation site (n=40). The remaining patients were used as the control group (n=40). The amount of postoperative bleeding was compared between the groups. Results: There were a total of 68 (85%) females and 12 (15%) males in the study. When bleeding was evaluated across the study and control groups, there was no significant difference in terms of the amount of postoperative bleeding (Study group: 73.0 ± 9.5 ml, Control group: 78.9 ± 18.3 ml) (P=0.332). The amount of bleeding showed a statistically significant difference across the different types of goiter (P=0.001). Conclusion: Utilization of Surgicel following thyroidectomy operation does not demonstrate any advantage over conventional methods of hemostasis (electrocautery, ligation).

Keywords: Oxidized cellulose, hemostasis, surgicel

Introduction

Thyroidectomy is a commonly performed operation in general surgery practice. Following thyroidectomy, bleeding and hematoma development have great significance due to the extensive vascularization of the thyroid tissue, and its proximity to the airway [1]. This complication can emerge as a life-threatening condition, and the incidence of bleeding after thyroidectomy has been reported in varying rates from 0.5% to 4.3% [3, 4]. Recognition of subtle signs of hematoma and early intervention for its drainage can save the patient from emergency surgery [2].

Throughout the history of surgery, various methods have been used for hemostasis in parallel to technical improvements. These techniques include ligation, monopolar-bipolar cautery, vascular ligation clips, electrothermal bipolar vessel sealing system (LigaSure™), ultrasonic active scissor (Ultracision™ harmonic scalpel), oxidized cellulose (Surgicel™), tissue adhesives, anti-fibrinolytics, surgical patch coated with human coagulation factors, blood stopper (Ankaferd™), hydroxylated polyvinyl acetal tampon, and fibrin and collagen sealants. The purpose of all these techniques is to prevent bleeding, stop bleeding as it happens, and to prevent development of a postoperative hematoma [5-9].

In this study, we aimed to investigate the hemostatic efficacy of Surgicel (Ethicon, Johnson & Johnson, Somerville, NJ), an oxidized cellulose, for the prevention of bleeding after thyroidectomy.

Materials and methods

This study was designed as a prospective clinical study in order to evaluate the efficacy of Surgicel™. Approval was obtained from the ethics committee. Written consent was obtained from patients participating in the study. Patients that underwent total thyroidectomy operation due to multinodular goiter in General Surgery clinic of our hospital between September 2012 and September 2015 were included in this study. Those that required surgery due to relapse were not included. Classification of goi-

Table 1. WHO goiter classification

Grade 0: No goiter presence is found
Grade 1a: the thyroid gland, however palpable, remains invisible, even in full extension of the neck (the thyroid not enlarged)
Grade 1b: goiter-palpable in normal position and visible in the upright position (full extension) of the neck; nodular goiter are also classified into this size range, even if they do not meet the criteria of enlarged thyroid gland
Grade 2: goiter-visible in normal position of the neck; no palpation required to diagnose thyroid enlargement
Grade 3: very large goiter, clearly visible from distance

Table 2. Comparisons between the groups

	Study group (n=40)	Control group (n=40)	P
Age: Mean ± SD (years)	46 ± 8.3	44.8 ± 10.6	[1]0.561
Sex: Female/Male (ratio)	32/8 (4)	36/4 (9)	[2]0.348
Goiter types			
Grade 1 (n=19)	11	8	[3]0.287
Grade 2 (n=41)	22	19	
Grade 3 (n=20)	7	13	
Drained Amount: Mean ± SD (ml)	73.0 ± 9.5	78.9 ± 18.3	[4]0.332
Min-Max (Med)	55-95 (70)	55-140 (75)	

[1]t test, [2]Fisher's exact test, [3]Chi-square, [4]Mann Whitney test, SD: standard deviation, Min: Minimum, Max: Maximum, Med: Median.

ter was made according to World Health Organization (WHO) criteria (**Table 1**).

Operation technique

Thyroidectomy operation was performed using a classical collar incision described by Kocher, and the thyroid was exposed between the anterior thyroid muscle group after incision of the epidermis, dermis, and platysma muscle. The upper and lower poles were released using free ligations in all cases. During the operation, bleeding control was maintained using monopolar and bipolar electrocautery. Operations were performed by a single surgeon, following same surgical principles. Patients were divided randomly into two groups. The block randomization was performed with an internet-based application (www.randomization.com).

Sixty four patients were selected over 1000 as sample group to determine the 5-10% of variability with a confidence interval of 90-95%. 16 patients were added to become 80 in total to reduce the margin of error in statistical evaluation.

Following thyroidectomy, one Surgicel™ was placed in each thyroid bed in 40 patients (Study group). For the other 40 patients, no additional procedure was applied (Control group). A drain was placed in all groups, and the amount of blood drained was measured and recorded daily during the postoperative period. When the drainage of blood declined to a level below 25 cc, the drain was removed and the patient was discharged on the same day. Demographic properties such as age and sex, postoperative complications, and hospital stay length were recorded.

Statistical analysis

Statistical analysis was carried out on IBM SPSS Statistics 22 (IBM SPSS, Turkey) software. Descriptive statistics were expressed as mean and standard deviation for continuous variables, and as count and percentage for categorical variables. When evaluating normally distributed data, a t-test was used for comparing parametric data between two groups, and ANOVA test was used for comparing parametric data across more than two groups. Comparison of non-normally distributed parametric data between groups was made with Kruskal Wallis test, and a Mann Whitney U test was used to detect the group that caused the difference. Comparison of qualitative data was made with chi-square and Fischer's Exact test. Results were evaluated within a 95% confidence interval, and a *p*-value of less than 0.05 was accepted as statistically significant.

Results

A total of 80 patients were included in the study; there were 40 patients (32 females and 8 males) in study group, and 40 patients (36 females and 4 males) in control group. There were 68 (85%) female and 12 (15%) male patients, and the mean age was 45.4 ± 9.5 years (**Table 2**).

Table 3. Comparisons according to operation indications

	Goiter Grade 1 (n=19)	Goiter Grade 2 (n=41)	Goiter Grade 3 (n=20)	P
Age: Mean ± SD (years)	43.4 ± 8.4	46.8 ± 9.7	44.2 ± 10.1	[1]0.367
Sex: Female/Male (ratio)	14/5 (2.8)	34/7 (4.8)	18/2 (9)	[2]0.303
Drained Amount: Mean ± SD (ml)	69.2 ± 9.5	71.1 ± 7.4	92.2 ± 18.3	[3]0.001*
Min-Max (Med)	55-95 (70)	55-85 (70)	70-140 (85)	

[1]ANOVA test, [2]Fisher's exact test, [3]Kruskal-Wallis test, SD: standard deviation, Min: Minimum, Max: Maximum, Med: Median, *$P<0.05$.

When patients were evaluated according to operation indications; 19 patients had Grade 1 goiter, 41 patients had Grade 2 goiter, 20 patients had Grade 3 goiter. Except two patients, all drains were removed on the second postoperative day.

Table 2 shows distribution of demographical properties according to groups. There was no difference between groups regarding age, sex, and operation indication (P=0.561, P=0.348 and P=0.287, respectively). When groups were evaluated for bleeding, the average amount of bleeding was 73.0 ± 9.5 ml in study group (Surgicel) and 78.9 ± 18.3 ml in control group. Although the average bleeding amount was lower in study group, the difference was not statistically significant (P=0.332).

When patients were evaluated according to their operation indications (**Table 3**), there were no significant differences in age and sex (P= 0.367 and P=0.303, respectively). Additionally, the amount of bleeding drained showed statistically significant difference across different operation indications (P=0.001). This difference was due to the higher amount of bleeding observed in patients with Grade 3 goiter in comparison to the other indication types.

No complication was detected in study patients with a follow-up of an approximately 6 months.

Discussion

Studies report the frequency of life-threatening bleeding and related complications after thyroidectomy operations to be between 0.3 to 2.5%. Postoperative bleeding and hematoma can be observed if the bleeding is not properly controlled with ligation and cauterization during the operation or if the patient has bleeding diathesis [2]. These complications occur most frequently in patients with intrathoracic goiter and Graves' Disease [10]. Despite increased risk of bleeding in subtotal thyroidectomy or Graves' Disease that is associated with increased circulation in thyroid, studies report postoperative bleeding rates as low as 0.3-1% [11]. In the present study, we found that patients with Grade 3 goiter had higher amount of bleeding when we evaluated bleeding across different thyroidectomy indications.

Despite technological advances; improvements in surgical tools and better understanding of the underlying thyroid pathologies, postoperative bleeding, and hematoma formation are still life-threatening complications that are rare but devastating [11, 12]. They may be caused by various factors including hemostasis method, the drain, and patient-related risk factors that may cause bleeding (hyperthyroidism causing thyroid congestion, tumor, and increased circulation in thyroid gland) [13, 14]. Precise and careful hemostasis is important in all kinds of surgical procedures. Since the head and neck region has a rich blood supply and higher risk for bleeding, vessels should be carefully dissected and individually ligated for safe and rapid surgery [15, 16]. Even minor bleeding from small vessels can lead to major complications by disturbing visualization of the surgical area and making it difficult to differentiate the anatomical structures. In addition, improper management of bleeding necessitates further operations and results in increased morbidity [9]. Control and prevention of bleeding both during and after the operation remains a particularly important point. Numerous maneuvers and surgical hemostatic agents are used to minimize the risk of hematoma; however, none can substitute for careful hemostasis [2, 16]. Conventionally, hemostasis in thyroid surgery is achieved via clamping and ligation techniques, diathermy, clips, tampon, fibrin mesh, and gauze [7, 9]. During the last decade, new methods and technological devices have been introduced to provide primary and secondary hemostasis and to improve reliability of the treatment. Some of these methods are minimal invasive thyroidectomy, regional anesthesia and nerve monitoring, ultrasonic coagulation-dissection, vessel sealers performing hemostasis, and dissection [9, 17].

Auvinen et al. [6] investigated the efficacy of the anti-fibrinolytic drug tranexamic acid in the perioperative bleeding control during thyroid surgery; however, they did not find a significant effect of the drug on bleeding. Lachachi et al. [5] used fibrin adhesive and did not use drain in their study of 81 patients. They concluded that fibrin adhesives could be widely used in addition to a good hemostatic technique in thyroid surgery. One study has found collagen and thrombin gelatin to be 100% effective for the prevention of bleeding from retroneural arteries [13, 18]. Haas et al. [7] stated that a surgical patch coated with human coagulation factors is an effective and reliable hemostatic method for a variety of interventions. Hydroxylated polyvinyl acetal tampons have been shown to be effective in control of minor bleeding, elimination of fluids, and tissue dissection in thyroid surgery [9].

Regenerated oxidized cellulose has also been used as a hemostatic agent. One experimental study compared closed and open pore regenerated oxidized cellulose used in gastric mucosal bleeding in rabbits receiving anticoagulants. It was observed that closed pore oxidized cellulose provided more rapid hemostasis [19]. Another study demonstrated that non-regenerated oxidized cellulose had greater surface area and equal bactericidal effect in comparison to regenerated oxidized cellulose. In addition, it had superior *in vivo* hemostatic properties under non-heparinized and heparinized conditions. Due to its ease of use, biocompatibility and bactericidal features, oxidized cellulose is used in almost every field of surgery, whereas non-regenerated oxidized cellulose will probably be in more common use as additional clinical studies are made and clinical experience improves [20].

In one controlled randomized prospective study, it was shown that the use of oxidized cellulose hemostatic agent (Surgicel) was not superior to the hemostasis provided with conventional techniques (electrocautery and ligature); conversely, its use increased the amount of bleeding. The authors concluded that precisely and carefully performed surgery can be more effective than use of prophylactic hemostatic agents regarding reduction of bleeding [21]. There are also studies showing that use of Surgicel is effective for the reduction of bleeding after operations such as partial nephrectomy and presacral surgery [22, 23].

In our study, while the average amount of bleeding in Surgicel group was lower, there was no statistical difference compared to the control group. There have been reports of the development of foreign body reaction, confusion with abscess due to late resorption, and mimicry of recurrent colon cancer after use of Surgicel [24-26]. In our study, we did not detect any complication in follow-up of 6 months. Since our aim in this study was to investigate the efficacy of Surgicel in hemostasis, we did not aim to longer follow up. But such conditions should not be overlooked. Nevertheless, large-scale randomized studies are needed to evaluate both efficacy in hemostasis and postoperative complications.

We found a significant difference between different operation indications in terms of the amount of bleeding. Particularly patients with Grade 3 goiter had a greater amount of bleeding. To detect possible confounding errors caused by concentration of cases in a certain group, the study groups and operation indications were evaluated with statistical analysis and no difference was detected. In our study, a limited number of cases and disproportionate distribution of goiter types are the limitations to the study. Therefore, our findings should be confirmed with larger-scale studies.

Conclusion

In the present study, we did not detect a hemostatic effect of Surgicel after goiter operations. The use of Surgicel was not found to be more effective than conventional hemostasis methods. Nevertheless, large-scale randomized prospective studies including patients with standard goiter types are required to investigate its effectiveness.

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Disclosure of conflict of interest

None.

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References

[1] Corsten M, Johnson S, Alherabi A. Is suction drainage an effective means of preventing hematoma in thyroid surgery? A meta-analysis. J Otolaryngol 2005; 34: 415-17.

[2] Harding J, Sebag F, Sierra M, Palazzo FF, Henry JF. Thyroid surgery: postoperative hematoma--prevention and treatment. Langenbecks Arch Surg 2006; 391: 169-73.

[3] Ardito G, Revelli L, Guidi ML, Murazio M, Lucci C, Modugno P, Di Giovanni V. Drainage in thyroid surgery. Ann Ital Chir 1999; 70: 511-17.

[4] Frick T, Largiader F. Perioperative complications in thyroid gland surgery. Langenbecks Arch Chir 1991; 376: 291-94.

[5] Lachachi F, Descottes B, Durand-Fontanier S, Sodji M, Pech de la Clause B, Valleix D. The value of fibrin sealant in thyroid surgery without drainage. Int Surg 2000; 85: 344-46.

[6] Auvinen O, Baer GA, Nordback I, Saaristo J. Antifibrinolytic therapy for prevention of hemorrhage during surgery of the thyroid gland. Klin Wochenschr 1987; 65: 253-255.

[7] Haas S. The use of a surgical patch coated with human coagulation factors in surgical routine: a multicenter postauthorization surveillance. Clin Appl Thromb Hemost 2006; 12: 445-50.

[8] Guler M, Maralcan G, Kul S, Baskonus I, Yilmaz M. The efficacy of Ankaferd Blood Stopper for the management of bleeding following total thyroidectomy. J Invest Surg 2011; 24: 205-10.

[9] Dionigi G, Boni L, Rovera F, Dionigi R. Dissection and hemostasis with hydroxilated polyvinyl acetal tampons in open thyroid surgery. Ann Surg Innov Res 2007; 1: 3.

[10] Deveci U, Altintoprak F, Sertan Kapakli M, Manukyan MN, Cubuk R, Yener N, Kebudi A. Is the use of a drain for thyroid surgery realistic? A prospective randomized interventional study. J Thyroid Res 2013; 2013: 285768.

[11] Bergqvist D, Källerö S. Reoperation for postoperative haemorrhagic complications. Analysis of a 10-year series. Acta Chir Scand 1985; 151: 17-22.

[12] Burkey SH, van Heerden JA, Thompson GB, Grant CS, Schleck CD, Farley DR. Reexploration for symptomatic hematomas after cervical exploration. Surgery 2001; 130: 914-20.

[13] Zhu JQ, Li ZH, Gong RX, Wei T, Zhang H, Zhang WY, Yang XY, Luo YL, Gong S, Wu XY. Sequential defunctionalization followed by thyroxine supplementation as preoperative preparation of hyperthyroid patients undergoing thyroidectomy. Chin Med J 2008; 121: 2010-15.

[14] Tonante A, Lo Schiavo MG, Bonanno L, D'Alia C, Taranto F, Gagliano E, Sturniolo G. Haemorrhagic complications in thyroid surgery. Control of bleeding from retroneural vessels using collagen and thrombin gelatine granules. Chir Ital 2006; 58: 61-68.

[15] Bliss RD, Gauger PG, Delbridge LW. Surgeon's approach to the thyroid gland: surgical anatomy and the importance of technique. World J Surg 2000; 24: 891-897.

[16] Moumoulidis I, Martinez Del Pero M, Brennan L, Jani P. Haemostasis in head and neck surgical procedures: Valsalva manoeuvre versus Trendelenburg tilt. Ann R Coll Surg Engl 2010; 92: 292-94.

[17] Dionigi G, Bacuzzi A, Boni L, Rovera F, Piantanida E, Tanda ML, Diurni M, Carcano G, Bartalena L, Cuffari S, Dionigi R. Influence of new technologies on thyroid surgery: state of the art. Expert Rev Med Devices 2005; 2: 547-57.

[18] Ujam A, Awad Z, Wong G, Tatla T, Farrell R. Safety trial of Floseal(®) haemostatic agent in head and neck surgery. Ann R Coll Surg Engl 2012; 94: 336-39.

[19] Velázquez-Aviña J, Mönkemüller K, Sakai P, Sulbaran M, Chávez-Vargas C, Montalvo Javé E, Sobrino-Cossío S. Hemostatic effect of oxidized regenerated cellulose in an experimental gastric mucosal resection model. Endoscopy 2014; 46: 878-82.

[20] Lewis KM, Spazierer D, Urban MD, Lin L, Redl, H, Goppelt A. Comparison of regenerated and non-regenerated oxidized cellulose hemostatic agents. Eur Surg 2013; 45: 213-20.

[21] Amit M, Binenbaum Y, Cohen JT, Gil Z. Effectiveness of an oxidized cellulose patch hemostatic agent in thyroid surgery: a prospective, randomized, controlled study. J Am Coll Surg 2013; 217: 221-5.

[22] Lucarotti ME, Armstrong CP, Bartolo DC. Control of presacral bleeding in rectal surgery. Ann R Coll Surg Engl 1991; 73: 289-90.

[23] Abou-Elela A, Morsy A, Badawy H, Fathy M. Use of oxidized cellulose hemostats (Surgicel™) to support parenchymal closure and achieve hemostasis following partial nephrectomy. Surg Technol Int 2009; 18: 75-9.

[24] Ibrahim MF, Aps C, Young CP. A foreign body reaction to Surgicel mimicking an abscess following cardiac surgery. Eur J Cardiothorac Surg 2002; 22: 489-90.

[25] Melamed JW, Paulson EK, Kliewer MA. Sonographic appearance of oxidized cellulose (Surgicel): pitfall in the diagnosis of postoperative abscess. J Ultrasound Med 1995; 14: 27-30.

[26] Salmo E, Bisset R, Aldean I. Oxidized cellulose mimicking a recurrent colorectal cancer: report of a case and review of the literature. Colorectal Dis 2010; 12: 381-2.