

1                   **Clinical usefulness of the Valsalva maneuver to improve**  
2                   **hemostasis during thyroidectomy**

3                   **Keywords:** Valsalva manoeuvre, hemostasis, Surgical Drains,  
4                   thyroidectomy

5                   **Short title:** Valsalva maneuver in thyroidectomy

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7

8    **Abstract**

9    **Introduction** Bleeding after total thyroidectomy remains a rare event which affects early  
10    postoperative morbidity, occurring in 0.3% up to 4.2% of cases. Intraoperative bleeding is an  
11    unpleasant complication, and it is often easily manageable though postoperative bleeding may  
12    represent a life-threatening condition for the patient. The purpose of our study is to clarify the  
13    role of Valsalva manoeuvre, in order to reduce postoperative bleeding.

14    **Methods** Between January 2019 to February 2022 , 250 consecutive patients were listed for  
15    thyroid surgery at our surgical department. We selected 178 patients and divided them in two  
16    groups based on the execution of the Valsalva Manoeuvre.

17    **Results** The cohort is made up of one hundred and seventy-eight patients, divided into two groups  
18    based on the use of the VM. There is no difference in the duration of surgery between the two  
19    groups. In Group B there is a lower number reintervention for bleeding. In Group A there is a  
20    significant greater volume of drainage output than in Group B. The Correlation test used, confirms  
21    these results.

22    **Conclusion** Cervical hematoma can compromise the patient's life, so bleeding control is crucial.  
23    The use of a simple, and safe Valsalva Manoeuvre can improve postoperative course, giving a  
24    significant reduction of drainage output but does not prevent the risk of reoperation for  
25    haemorrhage.

26

27 **Introduction**

28 Total Thyroidectomy (TT) is one of the most performed operations in the world. In neck surgery, it  
29 is among the most important interventions, considering its complexity and diffusion<sup>1</sup>.

30 Despite innovative approaches in surgery and innovations in surgical instruments, bleeding after  
31 TT remains a rare event which affects early postoperative morbidity, occurring in 0.3% up to 4.2%  
32 of cases<sup>2</sup>. The causes are not to be found only in the complex anatomy of the anterolateral region  
33 of the neck, which is richly vascularized, but also in the strategies adopted to achieve perfect  
34 haemostasis in an operative field where the nearby anatomical structures must be preserved<sup>3</sup>.

35 Intraoperative bleeding is an unpleasant complication, that most of the time it is easily  
36 manageable and resolvable though it engages the surgeon and it might lengthen the operating  
37 times; in the other hand postoperative bleeding can instead represent a life-threatening condition  
38 for the patient. For this reason, the need to adopt all known methods and strategies to minimize  
39 postoperative bleeding. Over time, the use of new instruments, the use of Collagen-Fibrinogen-  
40 Thrombin Patch (CFTP), cellulose gauze and other Haemostatic agents have made it possible to  
41 reduce the incidence of postoperative bleeding and reintervention but not to cancel it<sup>4</sup>.

42 The purpose of our study is to clarify whether the routine intraoperative execution of a Valsalva  
43 manoeuvre (VM) may affect the detection of bleeding that would otherwise remain occult and  
44 therefore may manifest in the postoperative period.

45

46 **Methods**

47 Between January 2019 to February 2022 , 250 consecutive patients were listed for thyroid surgery  
48 at our surgical department. In order to evaluate the role of VM, all patients treated with minimally  
49 invasive approaches (Mini Invasive Video Assisted Thyroidectomy MIVAT) or with robot-assisted  
50 transaxillary thyroid surgery (RATS) were excluded in the cohort. Loboistmectomies were also  
51 excluded. Other exclusion criteria were the need for lymph node dissections, patient coagulation  
52 disorders and an high anaesthesiologic risk (ASA 3). We chronologically divided our cohort of 178  
53 patients into 2 non-randomized groups: Group A (n = 96 patients) in which no MV was performed,  
54 and Group B (n = 82 patients) who had VM performed at the end of the TT.

55 VM was performed after thyroid excision and after a first revision of haemostasis in the operative  
56 field. Thanks to the anaesthesiologist VM was achieved by applying an incremental PEEP (positive  
57 end expiratory pressure) up to 30cm H<sub>2</sub>O, and subsequently a new VM by setting the mechanical  
58 ventilator in manual mode through the APL (adjustable pressure-limiting) valve.

59 All patients were treated by a team with the same surgical approach with extensive experience in  
60 neck surgery, therefore all procedures were standardized.

61 The two groups are comparable in demographics data (Table 1).

|                     | <b>Group A (n=96)</b> | <b>Group B (n=82)</b> | <b>Overall (n=178)</b> | <b>p value</b> |
|---------------------|-----------------------|-----------------------|------------------------|----------------|
| <b>Age (Range)</b>  | 20-74                 | 18-74                 | 18-74                  |                |
| <b>Mean</b>         | 47.82                 | 45.51                 | 46,75                  | 0.143          |
| <b>Median (±DS)</b> | 49.5 (±14.49)         | 45.5 (±14.28)         | 48 (±14,36)            |                |
| <b>M F</b>          | 37/59                 | 28/54                 | 65/113                 | 0.543          |
| <b>BMI(Range)</b>   | 23-40                 | 24-41                 | 23-41                  |                |
| <b>Mean</b>         | 31.47                 | 32.28                 | 31.84                  | 0.130          |
| <b>Median (±DS)</b> | 30.5(±4.80)           | 33(±4.77)             | 32(±4.79)              |                |
| <b>ASA score</b>    |                       |                       |                        |                |
| I                   | 38/96                 | 35/82                 | 63/178                 | 0.675          |
| II                  | 58/96                 | 47/82                 | 115/178                |                |

62 *Table 1 Demographic data. BMI (Body Mass Index), ASA score (American Society of  
63 Anesthesiologists). Significance test used are T test in numerical variable, and chi-square tests for  
64 categorical variables. A p value of less than 0.05 was considered statistically significant.*

65 Haemostasis is reached with monopolar or bipolar coagulators, and LigaSure™ (LSJ Medtronic,  
66 Covidien product, Minneapolis, MN, USA) was also used to achieve better sealing of the vessels. In  
67 dangerous areas, vessel's ligation and application of small surgical clips is preferred to avoid  
68 recurrent laryngeal nerve injury.

69 At the end of the operation (after the execution of the VM in Group B), a human fibrinogen and  
70 human thrombin (CFTP) patch is always applied and 2 suction surgical drains are placed in the  
71 thyroid lodges.

72 After the surgery, and the anaesthesiologic awakening, the patient waits about 2 hours in the  
73 recovery room, with personnel assigned to check the patient and the drainage output. Sometimes  
74 a longer observation time is required. If there is a rapid filling of the drains, or symptoms such as  
75 dyspnoea, difficulty breathing, suffocation and smoothing of the jugule appear, then the patient  
76 quickly undergoes new surgery for revision of the haemostasis.

77 Primary outcomes considered include drainage volume, reoperation rate in the first 6 hours, and  
78 reoperation in the first 24 hours. The duration of the operation and the occurrence of other  
79 complications other than bleeding were also evaluated.

80 ***Statistic analysis***

81 T test in numerical variable, and chi-square tests for categorical variables was performed for  
82 statistical comparison of the groups. Phi Coefficient was calculated for association between  
83 dichotomous variables. Point-Biserial Correlation was calculated for correlation between variables  
84 dichotomous and continuous. A p value of less than 0.05 was considered statistically significant.

85

86 **Results**

87 The cohort is made up of one hundred and seventy-eight patients, divided into two groups based  
88 on the use of the VM. There are no statistically significant differences in age, sex, BMI (Body Mass  
89 Index), and ASA score (American Society of Anesthesiologists) between the two groups (p value>  
90 0.05 for all; Table 1).

91 In table 2, surgical and postoperative data are shown and analyzed. There is no difference in the  
92 duration of surgery between the two groups. On the other hand, it should be emphasized that in  
93 Group B there is a lower number of cases of both early (<6h) and late re-intervention within 24h.  
94 These results were not statistically significant. The average period of stay under observation in the  
95 recovery room was also slightly shorter in Group B, albeit not in a statistically significant manner.  
96 The results show that in Group A there is a significant greater volume of drainage output than in  
97 Group B, and that more frequently they are kept in place even on the second postoperative day.  
98 All patients included in this study underwent double suction drains placement in the right and left  
99 thyroid lodges, respectively.

|  | GROUP A (N=96) | GROUP B (N=82) | P VALUE           |
|--|----------------|----------------|-------------------|
| OPERATION LENGTH (MIN)                       | 126.11         | 126.78         | 0.416             |
| RECOVERY ROOM STAY (MIN)                     | 126.93         | 123.96         | 0.083             |
| REOPERATION (<6H)                            | 6/96           | 1/82           | 0.085             |
| REOPERATION (<24H)                           | 4/96           | 0/82           | 0.125             |
| DRAINAGE VOLUME (ML)                         | 79.38          | 56.67          | <b>&lt; 0.001</b> |
| PERMANENCE OF THE DRAINAGES BEYOND THE FIRST | 16/96          | 5/82           | <b>0.029</b>      |

| POSTOPERATIVE DAY    |      |      |       |
|----------------------|------|------|-------|
| HOSPITAL STAY (DAYS) | 2.22 | 2.15 | 0.175 |

100 *Table 2 Surgical and Post surgical data. Significance Test used is Chi-Square. A p value of less than*  
 101 *0.05 was considered statistically significant.*

102 In table 3, we used Correlation tests (Phi Coefficient between dichotomous variables and Point-  
 103 Biserial was between variables dichotomous and continuous), to evaluate the real contribution of  
 104 the VM during TT. The results obtained showing there is no significant correlation for early or late  
 105 reoperation, not even for the length of the drainage beyond the first postoperative day. On the  
 106 other hand, the correlation with the overall volume of drainage output was statistically significant.

107 *Table 3 Tests of Correlation. Phi Coefficient was calculated for association between dichotomous*  
 108 *variables. Point-Biserial Correlation was calculated for correlation between variables dichotomous*  
 109 *and continuous. A p value of less than 0.05 was considered statistically significant.*

|  | Φ VALUE | P VALUE |
|--|---------|---------|
| <b>REOPERATION (&lt;6H)</b>                          | -0.129  | 0.914   |
| <b>REOPERATION (&lt;24H)</b>                         | -0.140  | 0.938   |
| <b>PERMANENCE OF THE DRAINAGES ON THE SECOND DAY</b> | -0.163  | 0.970   |
|  | r VALUE | P VALUE |
| <b>DRAINAGE VOLUME (ML)</b>                          | -0.851  | < 0.001 |

110

111 Finally, in Table 4, we analyse the incidence of main complications during TT ( Postoperative  
 112 Hypoparathyroidism, recurrent laryngeal nerve palsy, Wound Infection ). The two groups were  
 113 homogeneous, so there are no significant differences between the groups and these complications  
 114 are not related to the application of VM. All patients included in this study had a 30-day follow-up  
 115 after surgery. All cases of hypoparathyroidism and cases of recurrent laryngeal nerve palsy  
 116 resolved during follow-up and were therefore deemed *transient*.

117 *Table 4 Most important complications during TT.*

|                        | GROUP A<br>(N=96) | GROUP B<br>(N=82) | P VALUE |
|------------------------|-------------------|-------------------|---------|
| <b>WOUND INFECTION</b> | 2/96              | 1/82              | 0.655   |

|   |       |      |       |
|---|-------|------|-------|
| <b>TRANSIENT<br/>POSTOPERATIVE<br/>HYPOPARATHYROIDISM,<br/><i>n</i> (%)</b> | 14/96 | 9/82 | 0.474 |
| <b>TRANSIENT RECURRENT<br/>LARYNGEAL NERVE<br/>PALSY, <i>n</i> (%)</b>      | 2/96  | 2/82 | 0.873 |

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119

120 **Discussion**

121 Total thyroidectomy and lymph node dissections of the neck are among the most common surgery  
122 performed at the cervical level and had low rates of morbidity and mortality. Bleeding after  
123 thyroidectomy is well known complication, but with improved surgical technique e meticulous  
124 hemostasis has become a rare occurrence. However, although it is a rare occurrence if it is not  
125 diagnosed early and managed correctly, it becomes potentially life-threatening.

126 Indeed, patients with postoperative cervical hematoma they required a new surgery and longer  
127 hospital monitoring <sup>5</sup>. Symptoms that arise are: respiratory distress, choking, difficulty swallowing  
128 and a feeling of constriction in the neck. In 72% of cases, postoperative hematoma occurs within 6  
129 hours after surgery and 89% of the time within 12 hours <sup>6 7</sup>. The risk of bleeding is affected not  
130 only by the patient's factors, but also by the underlying thyroid disease and the haemostatic  
131 techniques used.

132 The use of drains in thyroid surgery is still widespread. In our unit, all patients undergoing TT are  
133 routinely subjected to placement of a drain for the right thyroid lobe, and one for the left thyroid  
134 lobe and placed on suction. They are then removed in the first postoperative day or remain  
135 longer in case of too high an output.

136 Traditionally, the main purpose for the use of drains is to prevent postoperative complications  
137 evacuating postoperative hematoma or lymphatic fluid and to notify the surgeon as soon as  
138 possible. However, the use of drains may be omitted in uncomplicated cases because often the  
139 drained volume is very low and it may not be necessary, or why haemostasis was remarkably  
140 adequate during surgery <sup>8 9</sup>. In light of improvements in hemostasis techniques and increasing  
141 surgical skills, the value of drainage in thyroid surgery may again be questioned, but to date,  
142 numerous randomized trials have failed to solve this question <sup>10 11</sup>. However we believe that life-

143 threatening complications, such as postoperative bleeding, hematoma, compression of air  
144 passages or suffocation, can be more promptly signaled by the presence of drains, and guarantee  
145 the surgeon a more timely diagnosis and the patient a less rapid onset of symptoms associated  
146 with hematoma.

147 The VM is a fairly common procedure for detecting bleeding points during thyroidectomy  
148 procedures <sup>12</sup>. During VM, increased intrathoracic and intraabdominal pressures causing internal  
149 jugular vein distension and increasing internal jugular venous pressure. The venous hypertension  
150 that involves the large veins causes a involves also the vessels of the thyroid lobe, increasing  
151 blood flow and forcing any bleeding, which can be detected.

152 Tokaç et al suggest that intraoperative application of VM has no positive effects on postoperative  
153 hemorrhagic complication<sup>13</sup>, Beyoglu in 2020 recommends to keep airway pressure at 50 cm H2O  
154 for 22.5 s in order to a more efficacious intraoperative detection of bleeding points in patients  
155 undergoing total thyroidectomies <sup>14</sup>. Ozdemir affirms that The Valsalva maneuver helps to detect  
156 any bleeding point after Trendelenburg positioning<sup>15</sup>.

157 In our study, we considered how VM can help surgeons practicing TT. In order to reduce  
158 postoperative bleeding at the end of haemostasis phase we perform a double VM by applying an  
159 incremental PEEP up to 30cm H<sub>2</sub>O, and afterwards a new VM setting the mechanical ventilator in  
160 manual mode. The second shot, often show a new bleeding point so the surgeons can reach a  
161 clean and dry surgical field.

162 This procedure allowed us to have fewer re-operations both in the first 6 postoperative hours and  
163 in the following 24 hours. These data were not statistically significant in our study, while a  
164 significant difference was in the reduction of the total volume of drains and in a lower incidence of

165 permanence of the drains beyond the first postoperative day. VM did not affect any of the other  
166 complications examined.

167

168

169 **Conclusion**

170 The manifestation of a hematoma can be life-threatening causing a compression of the airway  
171 therefore severe bleeding control is crucial. Technological progress and the use of new hemostatic  
172 agents have contributed to reducing the incidence of this phenomenon. However, the use of a  
173 simple, economical and safe maneuver such as the VM can improve postoperative course, giving a  
174 significant reduction of drainage output but does not prevent the risk of reoperation for  
175 haemorrhage.

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<sup>1</sup> Gil Z, Patel SG. Surgery for thyroid cancer. *Surg Oncol Clin N Am.* 2008 Jan;17(1):93-120, viii. doi: 10.1016/j.soc.2007.10.014. PMID: 18177802; PMCID: PMC4389794.

<sup>2</sup> Harding J, Sebag F, Sierra M, Palazzo FF, Henry JF. Thyroid surgery: postoperative hematoma--prevention and treatment. *Langenbecks Arch Surg.* 2006 Jun;391(3):169-73. doi: 10.1007/s00423-006-0028-6. Epub 2006 Mar 23. PMID: 16555087.

<sup>3</sup> Pacilli M, Tartaglia N, Gerundo A, Pavone G, Fersini A, Ambrosi A. Energy Based Vessel Sealing Devices in Thyroid Surgery: A Systematic Review to Clarify the Relationship with Recurrent Laryngeal Nerve Injuries. *Medicina (Kaunas).* 2020 Nov 27;56(12):651. doi: 10.3390/medicina56120651. PMID: 33260912; PMCID: PMC7760641.

<sup>4</sup> Khadra H, Bakeer M, Hauch A, Hu T, Kandil E. Hemostatic agent use in thyroid surgery: a meta-analysis. *Gland Surg.* 2018 Aug;7(Suppl 1):S34-S41. doi: 10.21037/gs.2018.03.02. PMID: 30175062; PMCID: PMC6107599.

<sup>5</sup> Tartaglia N, Di Lascia A, Vovola F, Cianci P, Fersini A, Pacilli M, Pavone G, Ambrosi A. Bilateral central neck dissection in the treatment of early unifocal papillary thyroid carcinomas with poor risk factors: A mono-institutional experience. *Ann Ital Chir.* 2019;8

<sup>6</sup> Lang BH, Yih PC, Lo CY. A review of risk factors and timing for postoperative hematoma after thyroidectomy: is outpatient thyroidectomy really safe? *World J Surg.* 2012 Oct;36(10):2497-502. doi: 10.1007/s00268-012-1682-1. PMID: 22714575; PMCID: PMC3465547.

<sup>7</sup> Jeppesen K, Moos C, Holm T, Pedersen AK, Skjøt-Arkil H. Risk of hematoma after hemithyroidectomy in an outpatient setting: a systematic review and meta-analysis. *Eur Arch Otorhinolaryngol.* 2022 Aug;279(8):3755-3767. doi: 10.1007/s00405-022-07312-y. Epub 2022 Mar 16. PMID: 35294619; PMCID: PMC9249722.

<sup>8</sup> Abboud B, Sleilaty G, Rizk H, Abadjian G, Ghorra C. Safety of thyroidectomy and cervical neck dissection without drains. *Can J Surg.* 2012 Jun;55(3):199-203. doi: 10.1503/cjs.025710. PMID: 22449723; PMCID: PMC3364308.

<sup>9</sup> Ha EJ, Lee J. The effect of fibrin glue on the quantity of drainage after thyroidectomy: a randomized controlled pilot trial. *Ann Surg Treat Res.* 2022 Apr;102(4):177-184. doi: 10.4174/astr.2022.102.4.177. Epub 2022 Apr 5. PMID: 35475227; PMCID: PMC9010963.

<sup>10</sup> Tartaglia N, Pavone G, Luzzi V, Vovola F, Tricarico F, Pacilli M, Ambrosi A. How emergency surgery has changed during the COVID-19 pandemic: A cohort study. *Ann Med Surg (Lond).* 2020 Dec 5;60:686-689. doi: 10.1016/j.amsu.2020.12.001. PMID: 33312562; PMCID: PMC7719013.

<sup>11</sup> Li L, Liu W, Tao H, Chen H, Li W, Huang T, Zhao E. Efficacy and safety of negative pressure versus natural drainage after thyroid surgery: A systematic review and meta-analysis. *Medicine (Baltimore).* 2018 Aug;97(31):e11576. doi: 10.1097/MD.0000000000011576. PMID: 30075525; PMCID: PMC6081074.

<sup>12</sup> 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 May;92(4):292-4. doi: 10.1308/003588410X12664192076412. PMID: 20501015; PMCID: PMC3025209.

<sup>13</sup> Tokaç M, Dumlu EG, Bozkurt B, Öcal H, Aydın C, Yalçın A, Çakır B, Kılıç M. Effect of Intraoperative Valsalva Maneuver Application on Bleeding Point Detection and Postoperative Drainage After Thyroidectomy Surgeries. *Int Surg.* 2015 Jun;100(6):994-8. doi: 10.9738/INTSURG-D-15-00002.1. PMID: 26414819; PMCID: PMC4587529.

<sup>14</sup> Beyoglu CA, Teksoz S, Ozdilek A, Akcivan M, Erbabacan E, Altindas F, Koksal G. A comparison of the efficacy of three different peak airway pressures on intraoperative bleeding point detection in patients undergoing thyroidectomy: a randomized, controlled, clinical trial. *BMC Surg.* 2020 Apr 10;20(1):69. doi: 10.1186/s12893-020-00728-5. PMID: 32276609; PMCID: PMC7146896.

<sup>15</sup> Ozdemir M, Makay O, Icoz G, Akyildiz M. What adds Valsalva maneuver to hemostasis after Trendelenburg's positioning during thyroid surgery? *Gland Surg.* 2017 Oct;6(5):433-436. doi: 10.21037/gs.2017.07.09. PMID: 29142831; PMCID: PMC5676157.