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Bipolar Quantum Molecular Resonance versus Blunt Dissection tonsillectomy

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Abstract. *Bipolar Quantum Molecular Resonance versus Blunt Dissection tonsillectomy*. *Objectives*: This study compared a quantum molecular resonance tonsillectomy (QMRT) to a standard blunt dissection tonsillectomy (BDT) for effectiveness and safety.
Methodology: From January 2011 to September 2012, we recruited 80 children (ages 3 to 16 y) with paediatric obstructive sleep apnoea syndrome and/or recurrent tonsillitis. Patients were randomly assigned to receive QMRT (N=40) or BDT (N=40). The operating time and blood loss during surgery were evaluated. During the first postoperative week, the patients' parents completed a questionnaire to evaluate bleeding, ear and neck pain, nausea, vomiting, interrupted sleep, oral liquid intake or discomfort in fluid assumption, and analgesic consumption.
Results: The average tonsillectomy duration was significantly shorter in the QMRT group (22.07 min±9.05) than in the BDT group (35.12 min±13.32; $p<0.000005$). The average blood loss during tonsillectomy was significantly lower for the QMRT group (5.62 ml±7.44) than for the BDT group (43 ml±33.20; $p<000000001$). However, the BDT group reported significantly lower pain scores than the QMRT group on days 2 ($p<0.05$), 5 ($p<0.05$), and 6 ($p<0.05$); on other days, the groups were not significantly different. The BDT group reported two early and one late bleeding episodes; the QMRT group recorded only two late bleeding episodes.
Conclusions: QMRT significantly reduced the operating time and intra-operative blood loss. No significant differences were found between the two techniques in postoperative pain or bleeding.

Introduction

Tonsillectomy is one of the most common operations performed in otolaryngology worldwide. For many years, the standard approach to tonsillectomy has been blunt dissection, followed by electrocautery haemostasis.[1] Tonsillectomy is the second most common head and neck surgery performed on children under the age of 15 y.[2] The use of diathermy to achieve intra-operative haemostasis was introduced in the 1960s[3] and has been widely adopted. In addition to this classic technique of blunt dissection (BDT)[4] with bipolar diathermy for haemostasis, many techniques have been developed more recently to simultaneously cauterize and dissect, including the use of bipolar diathermy forceps, scissors,[5-6] or coblation.[7] Several controversies have arisen on the outcomes of these new techniques, mainly regarding the incidence of complications, like pain and postoperative bleeding.[8]

Quantum molecular resonance tonsillectomy (QMRT) is among the recent innovations in the field of diathermy tonsillectomy. This technique takes advantage of a spectrum of quantized high frequencies. At temperatures below 50°C, this high frequency resonance can cut through tissue by breaking intercellular molecular bonds; simultaneously, it activates fibrinogen, which initiates the coagulation cascade. According to current literature, only three studies have investigated QMRT efficacy,[9-11] and only one compared outcomes between QMRT and BDT. Conflicting results on these and other surgical techniques, such as total or subtotal electrocautery tonsillectomy, have impeded recommendations for a gold standard technique for tonsillectomy.

Growing interest has focused on the relationship between surgical techniques and clinical outcomes, mostly in children affected by chronic diseases, such as adenotonsillar hypertrophy (ATh). The choice of appropriate surgical approaches in terms

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of pain and postoperative bleeding poses a great clinical challenge.[8] Pain is one of the most common complaints after tonsillectomy, and it may be so severe that it prevents adequate hydration. Pain-induced dehydration accounts for approximately 1% of the readmissions required for patients that received tonsillectomy.[12] Multiple techniques have been advocated for reducing postoperative tonsillectomy pain.

Currently, the relationship between QMRT and clinical outcomes in children remains poorly explored. We hypothesized that QMRT would be less painful than BDT in the first week after surgery, based on a visual analogue scale. This study aimed to compare QMRT and BDT in terms of short- and long-term outcomes and complications in children with ATh[13] associated with recurrent tonsillitis and/or moderate to severe obstructive sleep apnoea syndrome (OSAS).

Materials methods

Patients

In this prospective, single-blind study, from January 2011 to September 2012, we recruited all consecutive outpatients diagnosed with either paediatric OSAS associated with ATh or recurrent episodes of severe tonsillitis. This study was approved by the Ethics Committee of the University Hospital, P. Giaccone of Palermo. All of the patients' parents provided signed, informed consent. In accordance with Italian law, respect of individual privacy concerning clinical data was guaranteed.

One week before surgery, we collected a detailed clinical history, and we performed a complete physical examination, including nasal and oral endoscopy. Patient blood samples were drawn for laboratory tests, which included a complete blood count, prothrombin and thromboplastin time, and a fibrinogen assay. Patients were eligible for enrolment in the study when they had received a diagnosis of ATh (with tonsillar hypertrophy grades III-IV)[13] that required tonsillectomy. The indication for surgery was given on the basis of the Italian Guidelines for Tonsillectomy and Adenoidectomy (SNLG),[14] which required the presence of OSAS with an apnoea–hypopnoea index (AHI) >1 or the presence of >5 episodes of tonsillitis per year that prevented normal activities and symptoms that had persisted for at least one year. All patients with obstructive sleep symptoms underwent a hospital inpatient polysomonographic study in a paediatric sleep study centre. Patients were excluded when they reported one or more concomitant conditions, including diabetes, cardiac conduction abnormalities, electrolyte abnormalities, liver or kidney failure, past asthma symptoms, acute respiratory infections, anatomic nasal disorders, nasal polyps, craniofacial abnormalities, or neuromuscular disorders. None of the included patients had a retrotonsillar abscess.

Patients were randomly assigned to undergo a QMRT or BDT (Figure 1). The patient ages ranged from 3 to 16 y in both groups. After randomization, the QMRT group (40 children) included 21 patients with OSAS and 19 with recurrent tonsillitis; the BDT group (40 children) included 22 patients with OSAS and 17 with recurrent tonsillitis.

Post-surgery questionnaires

Upon discharge, Amoxicillin (twice per day for one week) was prescribed to patients with pain levels rated grade III and above. A cold liquid diet was recommended for all patients.

During the first week after surgery, the patients' parents completed a standardized diary to record symptoms and signs (bleeding, ear pain, neck pain, nausea, vomiting, interrupted sleep), rated on a four-point scale, where 0 denoted 'none', 1 denoted 'mild', 2 denoted 'moderate', and 3 denoted 'severe'. Discomfort in fluid/oral consumption was coded on a four-point scale, where 0 denoted 'no intake', 1 denoted 'sips', 2 denoted 'takes with pain', and 3 denoted 'takes without pain'. Patients rated the degree of pain (0 to 5) at three different times during the day (morning, after lunch, and evening) with the Wong-Baker Faces Pain Rating Scale.[15] This scale, designed for children ages 3 y and older, consisted of six simple face drawings, which represented a scale from 'no pain' to 'the worst pain you could ever imagine'. Patients pointed to the face that best described their pain. Daily pain was evaluated as the average of the three values taken each day.

During the post-operative period, oral fluid intake was evaluated as the time spent to drink 50 ml of water, starting at 5 h after the end of surgery. Post-operative pain was evaluated in two patient groups: those that requested and those that did not request analgesics. Paracetamol 15 mg/kg

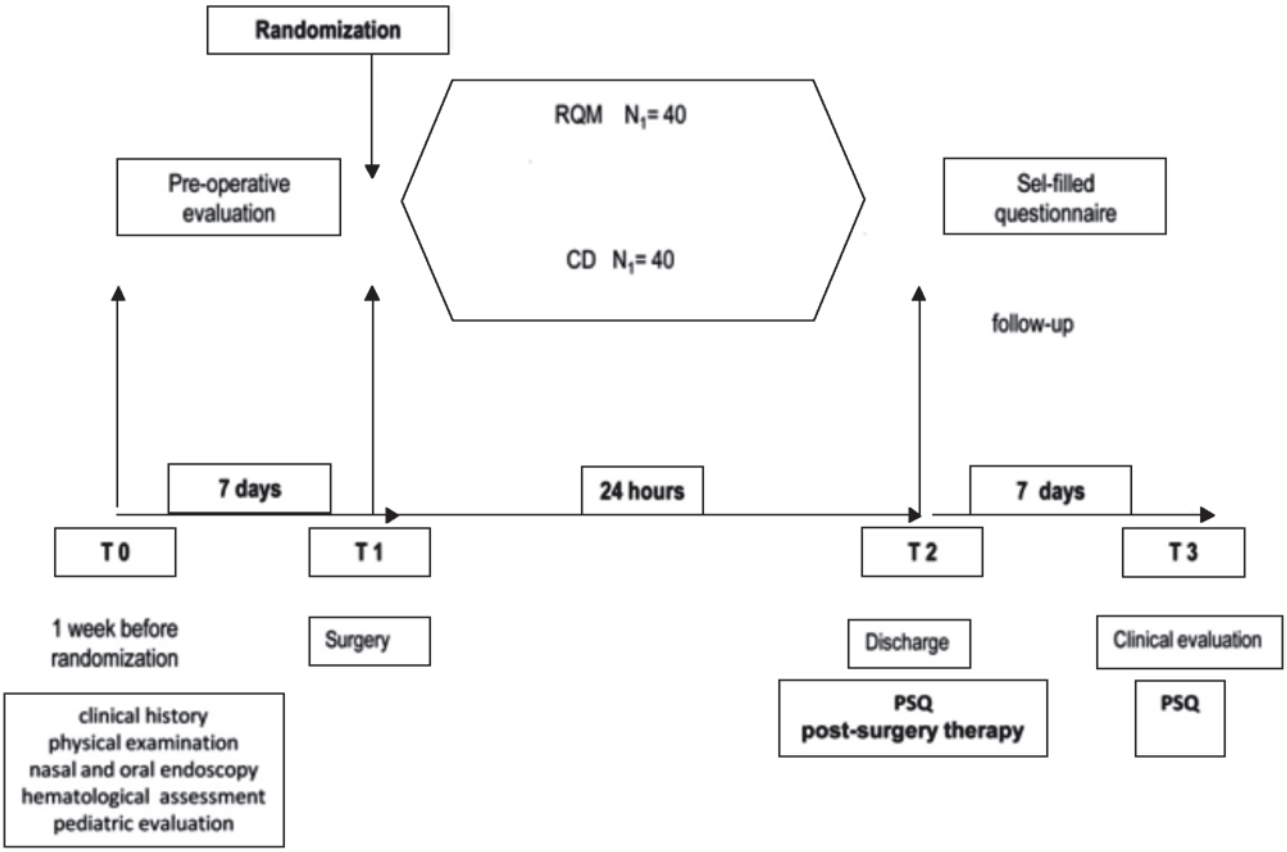

Figure 1
Study design T0 (time of admission), T1 (time of randomization and surgery), T2 (time of discharge), T3 (time of control), Quantum Molecular Resonance Tonsillectomy (QMRT), Blunt Dissection Tonsillectomy (BDT).

was administered, no more than 3 doses per day, to patients that requested analgesics. The patients' parents recorded all pain medication consumed at home during the first post-operative week. The questionnaires were returned at the control visit (after one week) (Figure 1).

Surgical procedures

All patients underwent general, balanced anaesthesia and they received an intra-operative dose of analgesia (paracetamol 15 mg/kg) and dexamethasone (0.5-1 mg/kg, maximum dose: 8 mg). Patient heart rate, blood pressure, and oxygen saturation were monitored throughout surgery.

For QMR tonsillectomy, an extracapsular dissection was performed with a QMR tool (Vesalius, Telea Elettronica Biomedica) equipped with a specific, angled pair of bipolar forceps (power setting, 4.5). Vesalius is an electronic tool that cuts and coagulates by generating a series of high-frequency waves, characterized by a major 4 MHz wave and subsequent 16 MHz waves with decreasing amplitude and increasing frequency.

To remove the tonsil, an incision was made by placing the forceps in the plane between the tonsil and the underlying musculature. After identifying the capsule, the dissection was carried out with simultaneous coagulation. Any further bleeding in the tonsillar fossa was stopped with point haemostasis performed with the QMR bipolar forceps.

The BD tonsillectomy was performed by making an incision in the mucosa of the anterior palatine pillar. Once the capsule was identified, the tonsil was dissected from the surrounding tissue with a blunt dissector, and the inferior pole was amputated with a snare. Haemostasis was performed with swabs, suction, and bipolar forceps to electrocoagulate any open vessels.

During the tonsillectomy, all patients also underwent a trans-oral, cold-dissection adenoidectomy. Haemostasis in the adenoid bed was performed with swabs soaked in hydrogen peroxide; 10 patients required bipolar cauterization (25 watts).

No surgical specimens were collected.

For all patients, at the conclusion of surgery, a nasogastric tube was inserted, and stomach contents were suctioned. Both surgical procedures were carried out by three expert, experienced surgeons. Children without complications were discharged on the day following surgery.

Peri-operative and post-operative measurements

The surgery duration was assessed for all patients. Blood loss was estimated by subtracting the amount of solution used for irrigation from the final amount of fluid suctioned at the end of surgery. We separately estimated blood loss during tonsillectomy and blood loss during adenoidectomy.

Post-operative bleeding was classified according to when it occurred; early bleeding occurred within 4 h of surgery; primary bleeding occurred within the first 24 h; and late bleeding occurred after 24 h. The importance of each bleeding episode was defined by the difficulty of haemostasis.[16-18] First degree (I) bleeding stopped spontaneously; second degree (II) bleeding was easily controlled with drugs or with manoeuvres that did not require anaesthesia; third degree (III) bleeding required a return into the operating room and general anaesthesia. Blood traces in saliva were not considered in evaluations of post-operative bleeding.

Statistical analyses

For descriptive statistics, results were expressed as absolute and relative frequencies for categorical variables or as the average ± standard deviation (SD) for continuous variables. Comparisons between qualitative parameters were performed with Mann-Whitney tests. A comparison of quantitative variables between the two groups of subjects (QMRT vs. BDT) was performed with the students' t-test. All tests were two-sided, and p-values less than 0.05 were considered statistically significant. Furthermore, p-values of $0.10 \geq p \geq 0.05$ were taken to indicate a statistical trend. Statistical analyses were performed with Microsoft Excel 2003 and imported into R 2.15.2.

Results

The cohort comprised 47 males and 33 females (Table 1). In both groups, ages ranged from 3 to 16 years. No statistically significant differences were found in sex, age, the presence of allergies, degrees of tonsil and adenoid hypertrophy, or body mass index.

The average tonsillectomy duration was significantly shorter in the QMRT group (22.07 min ± 9.05) than in the BDT group (35.12 min ± 13.32; $p < 0.000005$). Durations for adenoidectomy were not significantly different between groups (QMRT: 23.25 min ± 7.47 and BDT: 23 min ± 6.07). The duration of anaesthesia was also significantly shorter in the QMRT group (65.37 min ± 19.39) than in the BDT group (73.5 min ± 13.87; $p < 0.05$). During surgery, the heart rate, blood pressure, and oxygen saturation were not significantly different between groups.

The QMRT group lost significantly less blood during tonsillectomy (5.62 ml ± 7.44) compared to the average blood loss in the BDT group (43 ml ± 33.20; $p < 0.00000001$). The average blood loss during adenoidectomy was not significantly different between groups (Table 1). Early bleeding was only recorded in the BDT group (N = 2, Table 2). No primary bleeding was recorded. Late bleeding occurred in both groups (QMRT: N = 2, BDT: N = 1; Table 2). Haematic traces in saliva were observed in both groups during the first week (Table 2).

The time of first oral intake was similar between groups (QMRT: 6.6 h ± 1.01 and BDT: 6.75 h ± 1.46). No significant difference in analgesic consumption was found in the first 24 h post-operatively (Table 1).

Figure 2 shows a comparison of the signs and symptoms between groups. Compared to the QMRT group, the BDT group had significantly lower pain scores on days 2 ($p < 0.05$), 5 ($p < 0.05$), and 6 ($p < 0.05$); lower ear pain on days 5 ($p < 0.005$) and 6 ($p < 0.05$); and lower neck pain on days 1 ($p < 0.05$), 4 ($p < 0.05$), 6 ($p < 0.005$), and 7 ($p < 0.05$). The BDT group also had significantly less nausea on days 3 ($p < 0.05$), 5 ($p < 0.05$), and 7 ($p < 0.05$) and consumed less oral fluids on the first post-operative day ($p < 0.05$). No significant differences between groups were found in vomiting, sleep disturbances, or physical activity. A significantly higher number of patients required analgesics in the QMRT group on days 6 and 12; but more patients

Table 1

Demographic and clinical characteristics of the study patients

	QMRT	BDT	*p*
Gender: Male, n (%) Female, n (%)	20 (50%) 20 (50%)	27 (67.5%) 13 (32.5%)	0.1726
Age, y	6.67 ± 3.28	6.57 ± 3.63	0.89
BMI, kg/m^2	19.53 ± 5.42	19.90 ± 4.53	0.67
Allergy: Yes, n No, n	8 32	11 29	0.6
Tonsil Hypertrophy, grade (I-IV): %	III: 22 IV: 18	III: 19 IV: 21	0.65
Adenoid Hypertrophy (I-IV): %	III: 25 IV: 18	III: 27 IV: 13	1
Duration of Tonsils surgery, min.	22.07 ± 9.05	35.12 ± 13.32	0.000003
Duration of Adenoids surgery, min.	23.25 ± 7.47	23 ± 6.07	0.87
Anaesthesia time (min)	65.37 (19.39)	73.5 (13.87)	0.03
Tonsillectomy blood loss, ml	5.62 ± 7.44	43 ± 33.20	0.00000001
Adenoidectomy blood loss, ml	30.75 ± 28.06	29.75 ± 8	0.82
Time of first oral intake, h	6.6 ± 1.01	6.75 ± 1.46	0.73
24-h pain medication, n (%)	22 (55)	15 (37.5)	0.1782

Values indicate the mean ± SD, unless otherwise indicated. QMRT: Quantum magnetic resonance tonsillectomy; BDT: Blunt dissection tonsillectomy; BMI: body mass index.

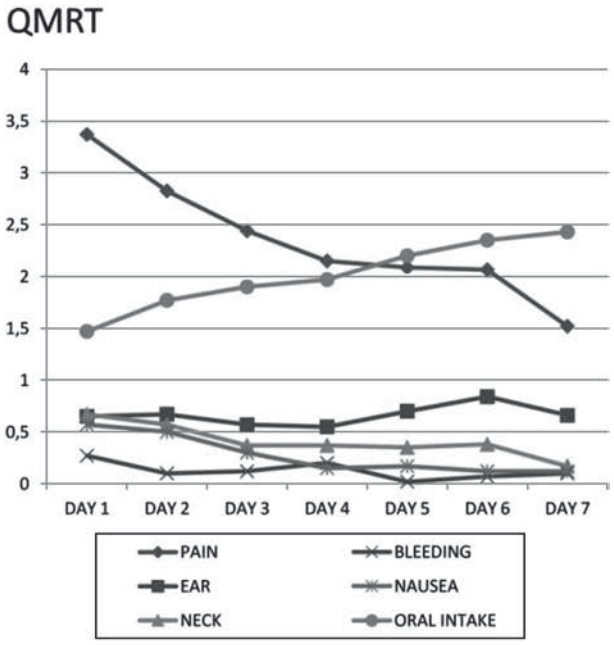

Figure 2

Comparison of pain, ear pain, neck pain, nausea and oral intake scores in group A (QMRT) during the first post-operative week. The degree of pain is from 1 to 5 according to the Wong-Baker Faces Pain Rating Scale. The pain localized to the ear and neck, bleeding and nausea ranging from 0 denoted none to 3 denoted severe. Fluid intake ranging from 0 denoted no intake to 3 denoted takes without any pain.

in the BDT group consumed analgesics on day 4 ($p<0.05$). All children that received analgesics only required a single dose.

We further evaluated the questionnaire data by considering only the patients with the highest scores. Thus, we compared patients in the two groups with levels 2 and 3 on the four-point scale for symptoms and signs and values ^{3}3 on the five-point pain scale. This evaluation showed that, among patients with the worst symptoms, the QMRT group experienced significantly greater pain on day 2 compared to those in the EDT group.

Finally, we compared patients within each group based on the indication for surgery. We found that the indication for surgery did not significantly affect the outcome.

Discussion

Tonsillectomy is one of the most common operations performed in otolaryngology worldwide. Moreover, both children and adults often require multilevel surgery for the treatment of OSAS.[19] For many years, the standard approach to tonsillectomy

Table 2
Postoperative bleeding

Bleeding class	QMRT N (degree/day)	BDT N (degree/day)
Early	0	2 (III/d1)
Primary	0	0
Late	2 (II/d6; III/d10)	1 (III/d5)
Haematic traces in saliva	N	N
Day 1	8	8
Day 2	3	2
Day 3	4	0
Day 4	7	0
Day 5	1	0
Day 6	1	0
Day 7	3	3

QMRT: quantum molecular resonance tonsillectomy; BDT: blunt dissection tonsillectomy.

has been blunt dissection followed by electrocautery haemostasis[20].

To reduce both the surgery time and the intra-operative blood loss, numerous techniques for tonsillectomy have been developed with diathermy. These techniques significantly reduced surgery duration and intra-operative bleeding, due to the simultaneous control of bleeding. However, these techniques appeared to increase the severity of post-operative pain, the delay in wound healing, and the rate of post-operative secondary haemorrhage. The relative risk of post-operative haemorrhage was 2-3 times greater for diathermy techniques than BDT, although the absolute risk difference was only 1-2%.[8] These complications resulted from the thermal tissue damage caused by the high temperatures (300°C) required for dissection and from the difficulties in controlling the depth of heat coagulation.[6]

A new tonsillectomy technique was recently introduced by D'Agostino *et al*.[9] that employed a quantum molecular resonance tool (Vesalius, Telea Elettronica Biomedica) with specific bipolar forceps. Vesalius is an electronic tool that cuts and coagulates tissue by generating alternating power and a series of high-frequency waves, characterized by a major 4 MHz wave and subsequent 16 MHz waves, with decreasing amplitude and increasing frequency. The energy quanta obtained were calibrated for human tissue to facilitate tissue cutting. Unlike the traditional electrocautery knife and laser, tissues were not cut by thermal vaporisation, but by breaking cellular molecular bonds. Moreover, with QMRT, coagulation is achieved through a process of fibrinogen protein denaturation. This denaturation triggers the physiologic coagulation cascade without requiring the necrotic plug created in warm techniques. As a result, cold cutting (<50 °C) is feasible, and the cut edges of tissues do not sustain thermal damage. Consequently, no tissue is sloughed off with QMRT. Thus, with QMRT, the surgeon can dissect, cauterize, and perform haemostasis simultaneously.

In the present study, we demonstrated the advantages of using QMRT over EDT. We found that QMRT required significantly shorter operating times (22.07 min±9.05) than BDT (35.12 min± 13.32). This advantage was due to the QMRT capability of simultaneous haemostasis, which saved considerable time. QMRT also required shorter anaesthesia times and smaller quantities of drug consumption. Thus, QMRT offered the opportunity to perform a greater number of interventions in a single operative session, which could reduce the cost of surgery. We also noted a significant reduction in intra-operative bleeding (QMRT: 5.62 ml±7.44 vs. BDT: 43 ml±33.20). This average reduction in blood loss (approximately 37 ml) was consistent with results from previous studies.[8,10] However, this reduction may be negligible, because a Cochrane review from 2001[20] showed that the difference in blood loss represented only 3% of the circulating blood volume of a 2-year-old child, and the percentage would be less in older children and adults. Nevertheless, the QMRT technique significantly facilitated the performance of surgery compared to BMT, because it was possible to work in a bloodless surgical field.

Consistent with recent literature,[9,11] we found that QMRT offered a slight, though not significant, advantage in post-operative bleeding. The QMRT group showed no early bleeding and similar late bleeding episodes compared to the BDT group. Also, the frequency of blood traces in saliva was similar between groups (Table 2).

It is known that, for about a week after adenotonsillectomy, the patient typically experiences pain, reflexotalgia, dysphagia, and odynophagia. As highlighted by Colclasure,[12] these conditions may result in dehydration, which accounts for up to 1% of all readmissions required

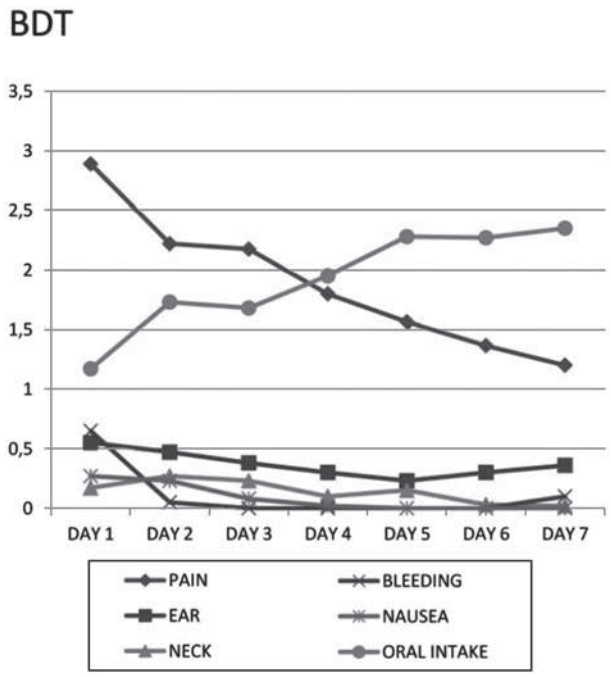

Figure 3
Comparison of pain, ear pain, neck pain, nausea and oral intake scores in B group (BDT) during the first post-operative week. The degree of pain is from 1 to 5 according to the Wong-Baker Faces Pain Rating Scale. The pain localized to the ear and neck, bleeding and nausea ranging from 0 denoted none to 3 denoted severe. Fluid intake ranging from 0 denoted no intake to 3 denoted takes without any pain.

for post-tonsillectomy patients. In the present study, we found no differences between groups in the timing of the first oral fluid intake or in analgesic consumption before discharge. We also monitored pain and associated disorders during the first post-operative week. When we considered all scores, we found that QMRT generally caused significantly more pain than BDT. In particular, significantly less pain was observed in the BDT than in the QMRT group on days 2, 5, and 7; less minor ear pain on days 5 and 6; less neck pain on days 1, 4, 6, and 7; and less nausea on days 3, 5, and 7. Analgesic consumption was significantly lower in the BDT group only on day 6, although the BDT group generally required less analgesics than the QMRT group. The only symptom favoured by QMRT was oral fluid intake; more fluid volume was consumed on the first day after surgery with QMRT than with BDT. No significant differences between groups were found in vomiting, sleep disturbances, or physical activity.

When only patients with the highest symptom scores were considered, we found the two techniques caused similar morbidity in the post-operative period. The only significant difference between groups was that the QMRT group experienced a higher level of pain on day 2 than the BDT group (3.43 ± 0.64 vs. 3.01 ± 0.39). The BDT was associated with low post-operative pain and rapid healing,[21] most likely because the surrounding tissues were not thermally damaged, except at sites treated with diathermy coagulation.

The current study was limited by the small sample size. Future studies should enrol a larger number of patients to improve the statistical power.

Conclusions

Our results showed that QMRT was a safe, effective, and comparable alternative to conventional BDT. QMRT had the advantages of significantly reducing the operating time and intra-operative blood loss. Only slight differences between the two techniques were observed in post-operative pain and post-surgical bleeding; the QMRT caused more pain than BDT.

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