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A Comparative Pilot Study with a New Design Instrument for Tonsillectomy

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ABSTACT

The most frequent and probably the earliest described surgical intervention of the ENT field is tonsillectomy. Various devices were invented to increase safety and decrease intraoperative and postoperative complications. A prospective, randomized, comparative pilot study with ethical approval and confirmed proposal code 5752) was designed as a built-in suction inlet dissector for tonsillectomy. This device is a relatively new instrument that has not been studied for tonsillectomy yet. Two hundred and thirty-one participants enrolled in the study: 119, 112 patients in the study group and control group, respectively. Intraoperative bleeding, operation time, pharyngobasilar fascia rupturing, pain and analgesic need, and starting diet outcomes compared between the two conventional and newly designed instruments. Data analyzed by a statistical data analysis tool, SPSS. The study revealed a significant difference in pharyngobasilar fascia rupturing in the study and control groups, respectively ($P<0.05$). Finally, relieving pain and diet starting time were found significant in favor of the study group. Although, there was no difference in intraoperative bleeding, operation time between the two groups. The study determined the feasibility of visualization of dissection and comparable outcomes. It needs more studies towards undertaking a clinical trial with more individuals comparing the devices.

Introduction

Tonsillectomy is one of the most commonly performed otorhinolaryngologic procedures. Its efficacy is well documented and different techniques and devices are used with no consensus regarding the optimal devices [1,2]. The general aim of tonsillectomy is the removal of tissue with minimum blood loss and minimal trauma to adjacent tissue [3]. There can be device difficulties associated with the operation, and serious complications may ensue [4]. In this study, we are using a different device with the previous shape and size but different capability and providing good visualization of the field of surgery to minimize intraoperative trauma and promoting patients' and physicians' postoperative satisfaction.

Materials and Methods

The general aim of adenotonsillectomy is the removal of the tissue with minimal trauma to adjacent tissue with different devices. The study was reviewed and approved by the research ethics committee of the Department of Otorhinolaryngology-Head&Neck Surgery, Iran University of medical sciences (IUMS) with a confirmed project code number: 5752. The reusable designed a modified Henke dissector with a built-in suction inlet with code number: US20130184717A1 produced by ENT research center and department, Rasool Akram hospital, (IUMS) approved for tonsillectomy. This comparative pilot study describes the device for the tonsillectomy procedure and its outcomes involving

adult and pediatric patients. Following hospital admission of two hundred thirty-one individuals (119 of the 55 female, 64 male in the study group, 112 of the 53 female, 59 male in the control group), 108 female, 123 male in groups, younger than 50 years, patients with appropriate history and physical examination entered on the permanent hospital record with informed consent. Hemograms, were performed and corrected values as within normal limits before surgery. Patients consecutively were scheduled for tonsillectomy 36.3% (84 patients), or adenotonsillectomy 63.6% (147 Patients) in IUMS hospitals from April 20, 2015, through May 10, 2020. 0ne hundred and nineteen participants were in the study group on reusable Modified Henke with built-in suction inlet dissector while 112 of all participants as the control group with a conventional Henke dissector, were operated respectively. The outcome of the device has not previously been published. We compared and assessed the two types of dissectors from the following perspectives: trauma to pharyngobasilar fascia as rupturing and non-rupturing one, operation time, bleeding, starting diet, pain, and analgesic need.

Results

The patients consecutively operated, data analyzed by a common statistical data analysis tool, SPSS. Hemograms, blood group & RH was about A- (2 female, 5 males,3%), A+(39 female, 45 male, 36.3%), AB+(10 female, 3 male, 5.6%), B-(1 male, 0.4%), B+(18 female, 32 male, 21.6%), O-(4 female, four male, 3.4%) and O+(35 female, 33 male, 29.4%) of the total individual. There was a statistically significant difference, eight patients (6.75 %), 19 patients (16.88%) experienced FBFR in the study and control groups, respectively ($P<0.05$). There was no difference in intraoperative bleeding between the groups, four patients (3.8%) and six patients (5.4%) in the study and control group respectively. Using the built-in suction inlet dissector reduced the duration of the operation, 16 minutes (7.714 mean SD±2.27) compared to the conventional Henke dissector, 20.77 minutes (8.474 mean SD±4.40), and however, this reduction was not significant. Finally, relieving pain (recorded numeric rating scale "NRS, 0–10" for determination of patients' pain concomitantly after starting liquid diet found to be significantly different $P<0.05$ in favor of the study group on the first postoperative day. No adverse events noted in both groups that were not either significant. There was no clear difference in postoperative infections or the need for reoperation in both groups.

Discussion

The general aim of surgery is to remove tissue with minimum blood loss and minimal trauma to adjacent tissue4. The efficacy of various devices is to increase safety and decrease intraoperative time, blood loss, and postoperative complications, however with no consensus regarding the optimal devices [1-4]. The study used a newly designed version of the Conventional Henke dissector to check whether to reduce complications and improve patients' safety, many devices designed. There was a statistically significant difference experienced in Pharyngobasilar fascia rupturing in study and control groups, respectively in favor of non-rupturing fascia that denotes providing better visualization keeps patients' anatomy safe. There was no difference in intraoperative bleeding between the groups comparing with other devices as many articles have assessed [5-8]. Tonsillectomies with different devices have not yet reached any consensus of shortening time regarding the optimal techniques with the lowest morbidity rates [9-11]. Decreasing pain postoperatively is a matter to patients to control by using a pain killer or as early as starting the diet [12]. The study showed that persevering tissues in the region as keeping safe pharyngobasillar fascia and minimal damage to surrounding tissue might slightly increase operation time but reducing bleeding in different aspects of tonsillectomy is not changed. Although no pain and early starting the diet is possible without discomfort. However, the reported results are, in many cases, conflicting and controversial [13-15]. In this study, using the new device reduced the duration of the operation compared to conventional one was not significant and was like as many other articles have been published [1,6,9].

All techniques and methods are interested in not damaging the surrounding tissues and focusing on providing safety. The main finding of the meta-analysis is not that any techniques used during the past decade in an attempting to decrease postoperative morbidity in terms of pain and bleeding provided any significant advantage over the conventional especially with precise devices [1,6,9]. The only outcome that differed significantly in two devices for tonsillectomies performed using the instruments was operation time was significantly related to pharyngobasilar rupturing [16]. Comparing the average operation times with each device was not statistically different. However, it is acceptable that data does not have any measurable clinical significance because of fewer participants and was not a randomized clinical trial. Earlier diet starting time in the study group suggests that relieving pain may be slightly less in this group at the first postoperative day as many other studies have published but did not show any significant difference [12]. Other articles showed that pain was significantly greater in other groups [16,17]. The clinical significance needs more investigation with the new instrument based on the issue in future studies.

Conclusion

This study concluded that pharyngobasilar rupturing with a build-in suction dissector reduces significant operation time; our suggestion is to have more RCTs to find out the results of the newly designed instruments with RF or coblation.

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