



Contents lists available at ScienceDirect

Surgery

journal homepage: www.elsevier.com/locate/surg

Quality of life after surgery in secondary hyperparathyroidism, comparing subtotal parathyroidectomy with total parathyroidectomy with immediate parathyroid autograft: Prospective randomized trial

Wellington Alves Filho, PhD^{a,*}, Willemijn Y. van der Plas, MD^b, Marilia D.G. Brescia, MD, PhD^a, Climerio P. Nascimento Jr, MD, PhD^a, Patricia T. Goldenstein, MD, PhD^c, Ledo M. Massoni Neto, MD^a, Sergio S. Arap, MD, PhD^a, Melani R. Custodio, MD, PhD^c, Rodrigo O. Bueno, MD, PhD^c, Rosa M.A. Moyses, MD, PhD^c, Vanda Jorgetti, MD, PhD^c, Schelto Kruijf, MD, PhD^b, Fabio L.M. Montenegro, MD, PhD^a

^a Head and Neck Surgery, Department of Surgery, Hospital das Clinicas HCFMUSP, Faculdade de Medicina, Universidade de Sao Paulo, Brazil

^b Department of Surgical Oncology, University Medical Center Groningen, the Netherlands

^c Nephrology, Department of Internal Medicine, Hospital das Clinicas HCFMUSP, Faculdade de Medicina, Universidade de Sao Paulo, Brazil

ARTICLE INFO

Article history:
Accepted 27 June 2018
Available online xxx

ABSTRACT

Background: No prospective randomized data exist about the impact of various strategies of parathyroidectomy in secondary hyperparathyroidism patients on quality of life and its possible relationship with metabolic status after the operation.

Method: In a prospective randomized trial, the Short Form 36 Health Survey Questionnaire was applied to 69 patients undergoing parathyroidectomy through various approaches: subtotal parathyroidectomy ($n=23$), total parathyroidectomy (PTx) with autotransplantation of 45 fragments ($n=25$) and PTx with autotransplantation of 90 fragments ($n=21$). The questionnaire was completed at three moments: (1) preoperatively, (2) 6 months after surgery, and (3) 12 months after surgery.

Results: Quality of life improved significantly in the physical component summary score in all three groups. Subtotal parathyroidectomy scores changed from 30.6 preoperatively to 51.7 6 months after surgery and 53.7 12 months after surgery. Total arathyroidectomy with autotransplantation of 45 fragments scores changed from 33.8 preoperatively to 52.6 6 months after surgery and 55.2 12 months after surgery. Total parathyroidectomy with autotransplantation of 90 fragments scores changed from 31.8 preoperatively to 50.5 6 months after surgery and 55.2 12 months after surgery (all groups $P < .0001$). No significant difference was detected in the physical component summary score change among the three groups. The physical component summary score was negatively correlated to age, parathormone, and alkaline phosphatase preoperatively.

Conclusion: Parathyroidectomy significantly improves quality of life in hemodialysis patients with secondary hyperparathyroidism, regardless of the type of operation.

© 2018 Elsevier Inc. All rights reserved.

Introduction

Among patients with end-stage renal disease (ESRD) undergoing dialysis, a true cure is not always possible. For this reason, mental and physical wellbeing should always figure among the main purposes of care.¹ Complications of ESRD, such as secondary

hyperparathyroidism (SHPT), should be treated accordingly, as they might increase mortality and have a major impact on quality of life (QoL) in such patients.²

Advanced SHPT includes symptoms such as fatigue, bone and joint pain, pruritus and headache. In addition, some patients can develop spontaneous fractures, ectopic calcifications, and neuromuscular and psychiatric manifestations.³ These problems may have an impact on QoL in SHPT patients.^{4,5}

Surgical treatment for SHPT is indicated when clinical management becomes medically refractory.^{6,7} Parathyroidectomy corrects serum calcium, alkaline phosphatase, and parathormone (PTH)

* Corresponding author: University of Sao Paulo Medical School, Head and Neck Department, rua da Paz 220 ap 302, Fortaleza-CE, Brazil, 60165-180.

E-mail address: wellington_ufc@yahoo.com.br (W.A. Filho).

levels and improves symptoms that can affect QoL, such as bone pain.³

Three approaches are available for the surgical management of SHPT: subtotal parathyroidectomy,⁸ total parathyroidectomy (PTx),⁹ and PTx with immediate heterotopic autograft.^{10–13} Less than subtotal parathyroid resection is not routinely considered as a satisfactory option in SHPT. In 1991, subtotal parathyroidectomy and PTx with immediate autograft were compared in a prospectively randomized study. Although the authors concluded that PTx with an autograft was superior to subtotal parathyroidectomy, they unfortunately did not compare PTH levels, which are currently a very important parameter in the evaluation of SHPT treatment.¹⁴ QoL was also not addressed in that study.

Previous studies have documented the use of tools to measure QoL in patients with ESRD. The Short Form 36 Health Survey Questionnaire (SF-36) is a valid instrument for these individuals¹ and may also be a powerful predictor of morbidity and worse outcomes in dialysis patients.¹⁵

Even though various studies have assessed QoL in primary hyperparathyroidism,^{16–20} few studies have measured QoL in patients with SHPT. Although these studies indicate the improvement of QoL after the operation, they often have shortcomings, such as enrolling only a few patients,^{21–22} performing only one type of operation,²³ or nonrandomized series.^{24–26}

To the best of our knowledge, no clear information has been collected from a single prospective randomized study that compares QoL before and after parathyroidectomy, according to the various surgical approaches currently accepted.

Materials and Methods

Subjects were enrolled from a current clinical research trial developed at the University of Sao Paulo Medical School, Brazil, entitled “Subtotal parathyroidectomy or total parathyroidectomy with autograft in chronic kidney disease patients under dialysis,” a randomized clinical trial comparing various parathyroidectomy strategies registered at Clinicaltrials.gov (NCT02464072). This is a parallel group trial with a 1:1:1 allocation. This main study has three arms: subtotal parathyroidectomy and two variants of PTx with immediate autograft in the forearm, one group with autograft of 45 fragments of parathyroid tissue and the other group with twice the number of parathyroid fragments implanted (90 fragments). The primary end point of this study was survival after the operation. To disclose a difference of 0.3 in survival at 5 years after the operation and considering a 15% rate of patients missing follow-up, we estimated the inclusion of approximately 41 patients in each of the three arms for a statistical power of 80% and a significance level of 5%. The same group of surgeons performed the three types of surgical techniques for SHPT. These techniques were widely established as adequate for treating the condition, but there was no information available on the best approach regarding overall survival and adequate PTH levels after surgery. Randomization was generated by computer software (MS-Excel 2007, Microsoft, Redmond, WA, USA) and the operation type was stored in a concealed opaque envelope that was opened at the induction of anesthesia.

The present study is part of this study and it has its own approval of the University of Sao Paulo Medical School's institutional review board. The primary end point is QoL by determining whether there is a significant difference in change of QoL among patients with SHPT undergoing subtotal parathyroidectomy or PTx with immediate autograft. For this end point, no new sample estimates were calculated. In addition, we evaluated the degree of change in QoL after surgery, degree of improvement, and its possible relation to biochemical markers, before and after the procedures.

Eligible patients were those with ESRD on dialysis who had an indication for surgical treatment of SHPT, fulfilling one or more of the following criteria: (1) high PTH levels (> 500 pg/mL), (2) the detection of one or more enlarged parathyroid gland (>500 mm³ or diameter greater than 1 cm), (3) hypercalcemia (>10.2 mg/dL) and/or hyperphosphatemia (>6 mg/dL). Subjects with severe symptoms, ectopic calcifications, erythropoietin resistant anemia, or dilated cardiomyopathy were also referred to surgery. These patients were followed at the Renal Osteodystrophy Unit, Section of Nephrology of the Department of Internal Medicine of the University of Sao Paulo Medical School. The decision for surgical referral was made solely by nephrologists. All dialysis patients with indications for parathyroidectomy were invited to participate in the study by the surgeons. Patients who agreed to participate signed the informed consent form. Subjects who did not agree to participate, those who underwent a successful kidney transplant after parathyroidectomy, or those who demonstrated immediate failure to surgical treatment of SHPT (persistence, represented by an insufficient decrease of PTH few days after the procedure)²⁷ or late recurrence of SHPT (defined as PTH levels higher than 9 times the upper limit of normality after 6 months postoperatively), were excluded from the study.

After hospital admission for surgery, patients were interviewed by the main investigator, using the SF-36 questionnaire to assess QoL preoperatively. Patients were randomly allocated to one of the three types of operation: subtotal parathyroidectomy, PTx with 45 fragments autograft, and PTx with 90 fragments autograft. PTx is the removal of all parathyroid glands, confirmed by frozen section histopathologic analysis. We select one of the glands to be the source of the parathyroid fragments that will be immediately implanted in the forearm. Each parathyroid fragment consists of a 2- × 1- × 1-mm tissue of the macroscopically non-nodular parathyroid gland. Subtotal parathyroidectomy, on the other hand, is the removal of parathyroid glands, while preserving an amount of parathyroid tissue of approximately 2 times the size of a normal gland, with its vascular pedicle also preserved. The same surgical team performed all operations. It consisted of residents, staff, and attending surgeons, including the main investigator, who followed a detailed protocol. All surgeons participating in the study were personally instructed by the principal investigator and adequately trained to perform the three types of operation. Postoperative care and hospital discharge were left to the discretion of the attending physician.

QoL was investigated using the SF-36 questionnaire and applied to subjects at three time points: (1) preoperatively, (2) 6 months after surgery, and (3) 12 months after surgery. Data were collected through direct interview (during hospital admission to surgery) and by telephone (6 and 12 months postoperatively). All interviews (preoperative and postoperative) were conducted by the main investigator.

SF-36 consists of 36 objective questions to assess patients' well-being through eight dimensions: physical functioning (PF), role-functioning physical (RP), bodily pain (BP), general health, vitality (VT), social functioning (SF), role-functioning emotional (RE), and mental health (MH). The scores varied from 0 to 100, and the higher the score, the better the QoL in terms of the dimensions studied. Two summary scores were also used: the physical component summary score (PCS)—calculated as the mean of the PF, RP, BP, and GH scores—and the mental component summary score (MCS)—calculated as the mean of the VT, SF, RE, and MH scores. Formulae for calculation of the SF-36 scores can be found at http://www.rand.org/health/surveys_tools/mos/36-item-short-form/scoring.html. The absolute change of PCS (Δ PCS) and the absolute change of MCS (Δ MCS) were calculated by subtracting the preoperative measurements from each value of

Download English Version:

<https://daneshyari.com/en/article/11013213>

Download Persian Version:

<https://daneshyari.com/article/11013213>

[Daneshyari.com](https://daneshyari.com)