ENDOPROSTHESES-RELATED COMPLICATIONS IN PATIENTS WITH BONE TUMORS OF THE KNEE

VINICIUS YNOE DE MORAES, GUILHERME CONFORTO GRACITELLI, FERNANDO CURY REZENDE, MARIA STELLA PECCIN DA SILVA, DAN CARAÍ MAIA VIOLA, REYNALDO JESUS GARCIA FILHO

ABSTRACT

Non-conventional endoprostheses (NCE) are frequently used in orthopedic oncology. The complications associated with this procedure have prompted research, due to the fact that it is commonly performed on young patients, with a higher survival rate. We conducted a systematic review of the literature, searching for the best scientific evidence on the subject. The research was carried out in the following databases: MEDLINE, EMBASE, CINAHL and the Cochrane Central Register of randomized controlled trials (CCTR), seeking to identify studies that report complications, and compare patellar resurfacing versus retention. The studies were selected according to the

best methodological quality that exists for the subject. One hundred and forty six (146) studies were evaluated. No randomized clinical trial was found. We conducted a qualitative and quantitative evaluation of the work found (evidence levels IV and V). We used the Mann-Whitney U test for the statistical analysis. The results indicate a need for further studies that will enable us to reach a more solid conclusion. The rate of complications after NCE can be considered high, despite the low quality of the studies, as demonstrated by the studies that exist in the literature.

Keywords: Bone neoplasms. Knee. Arthroplasty, Replacement, Knee. Osteosarcoma.

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INTRODUCTION

The use of non-conventional endoprostheses (NCE) for the treatment of bone tumors at knee level is a reality of orthopedic oncology. The fact that these lesions are frequent in young patients with a survival rate above 10 years prompts us to determine the best treatment method, especially for articular reconstruction of the knee.

The non-conventional endoprosthesis presents advantages in relation to the other methods, as it enables the preservation of the limb and its articular functions. ¹⁻³ It is also a fact that preservation of the limb is not associated with reduction of the survival rate of the oncological patient. ^{1,2} This makes it possible to recommend non-conventional endoprostheses in 85% of cases. ³⁻⁵

The questioning of the rate of complications inherent to the procedure, including - and especially – those related to the function of the extensor mechanism, arises in this scope. This is best resolved in a non-oncological population. ^{6,7} International literature describes several complications relating to patella replacement, such as patellar component loosening,

patellar fracture and rupture of the patellar tendon.^{6,8,9} In the real practice of orthopedic oncology, the approach to the topic involves obstacles since surveys focus on survival, resection size and functional scores of the affected limb, which transforms the topic into a field of research and exploration.^{1,2,5,10-12} However, it appears to us to be difficult to conduct clinical studies without multicentric collaboration. Systematic reviews are a summary of the literature that addresses the available data and promotes the acquisition of rational information for clinical decisions.¹³⁻¹⁵ The aim of this survey is to promote a systematic review to answer the following clinical questions: 1) Which is the rate of post-NCE complications? 2) Which is the contribution of patellar complications in this population?

MATERIALS AND METHODS

The following bases in the English, Spanish and Portuguese languages were investigated up to June 2009: MEDLINE; EMBASE; CINAHL; LILACS and the Cochrane Database of Systematic Reviews. The inclusion criteria are set out in Chart 1. The strategy of research for randomized clinical

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Universidade Federal de São Paulo - UNIFESP

Study conducted in the Department of Orthopedics and Traumatology of Escola Paulista de Medicina – UNIFESP/EPM – São Paulo, SP, Brazil. Mailing Address: Av. Onze de Junho, 685, Apto 66, Vila Clementino, São Paulo, SP, Brazil. CEP: 04041-052. E-mail: vym70@yahoo.com.br

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Chart 1. Basic methodological criteria for inclusion in studies.

- Study design: Randomized Clinical Trials, observational studies with established final outcome – complications (cohorts, case-control, case series);
- Study design with randomized intervention or different cohorts in follow-up or case series with defined complication outcomes;
- 4. Evaluation of associated criteria of functionality and quality of life;
- 5. Literature written in Portuguese, English and Spanish;
- 6. Publication until June 2009.

trials was used according to the methodology of the Cochrane collaboration.^{14,16}

A strategy was used to search for non-CCTR publications with the use of MeSH/DeCS terms (when available) and non-MeSH/DeCS terms. The terms used are described in Chart 2. When it proved impossible to use a MeSH/DeCS term, non-MESH terms were used. After the localization of studies congruent with the parameters to be analyzed, each eligible study was methodologically evaluated by two investigators (V.Y.M. and D.C.V) with inclusion and exclusion based on methodological criteria established by known instruments.^{17,18}

Chart 2. List of Terms used in the search strategy.

- 1. Knee
- 2. Osteosarcoma
- 3. Bone tumors or bone neoplasms
- 4. Replacement or resurfacing or substitution
- 5. Total knee replacement
- 6. Knee Prosthesis or Total knee prosthesis
- 7. Patella or Patellar
- 8. Comparative study, random allocation, randomized controlled trials, single blind method, double-blind method, controlled clinical trials, clinical trials
- 9. Endoprosthesis
- 10. Distal Femur
- 11. Proximal tibia
- 12. Arthroplasty

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RESULTS

One hundred forty-six (146) articles were analyzed. No randomized clinical trial was found. No allocation was found in different groups for the outcome proposed by this publication, both as primary or secondary outcome. Four studies were included in the analysis, as they represented the best evidence on the topic foreseen. A study was found referring to the topic of interest of this publication, treated as secondary outcome and with sample group identified by the authors as insufficient. The methodological characteristics, as well as the descriptive and inferential analysis of these studies, are summarized in Tables 1, 2 and 3.

DISCUSSION

The randomized clinical trials, preferred targets of systematic reviews on therapeutic approaches, have not yet been found for the topic in question. In the sphere of orthopedics, lengthy discussions have been held on the validity of and the need to conduct randomized clinical trials and there is a global effort to this end, especially when related to diseases of high complexity and of low prevalence, as is the case of malignant bone tumors. In this context, the ideal study design would be that of a clinical trial (multicentric), which would foresee complications as the outcome. ¹⁹

In this panorama, the use of the available literature appears to us to be evidence that should be valued, especially in clinical situations such as those that involve oncological populations. Accordingly, the results of this survey should serve as a parameter and as a possible tool to guide the external validity of probable studies on the subject generated by other investigators.

As concerns the research methods used for the project, we should be mindful of some selection biases. These are important biases: the language restriction, the absence of the search for unpublished and/or non-indexed surveys (example: conference annals). It also proved difficult, on certain occasions, to define and characterize outcomes,

Table 1. Characteristics of the publications included in the analysis.

Author, year	Site of performance	Type of study	Sample	Follow-up time	Relevant outcomes	Other information
Bickels, 2002 ¹⁹	Washington, USA (Washington Cancer Institute, Washington Hospital Center) Tel Aviv, Israel (Tel-Aviv University)	Case series	110 patients, age 10-80 years, mean age 21.5 years	Minimum of two years, mean time 7.8 years.	There was no systematized intervention	No routine replacement was performed; authors justify that they present a young sample group
Frink ³ , 2005	Houston, TX (University of Texas, M.D. Anderson Cancer Center)	Case series	83 patients, 13-77 years, mean age 25 years	Mean-146 months (62-252 months)	There was no systematized intervention.	They report 26 complications, one related to the failure of the patellar component *
Kawai, 1998 ²⁰	New York, USA (MSKCC)	Case series	40 patients, 12-68, mean age 25.6 years	Mean eight years (5-17 years)	There was no systematized intervention.	30 complications, two patellar fractures*
Schawb, 20068	New York, USA (Weill Medical College of Cornell University)	Case series	43 patients, mean age 41 years	40 months (10-101 months)	There was a comparison of 15 patients (with substitution) with 28 (without substitution). There was no statistical significance for the parameters evaluated ****	The decision to replace the patella was made in the intraoperative stage ***

^{*53} of the patients underwent replacement of the articular component of the patella (polyethylene)** Patellar osteotomy was performed in the intraoperative period in both cases.*** International Society Of Limb Salvage (ISOLS) score, range of motion, symptoms in the anterior region of the knee. **** The investigators considered the quality of the articular surface and patellar congruence/morphology in relation to the articular surface.

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Table 2. Metasynthesis of the studies included - complications

Study, year	Presence of post-NCE complications	Absence of post-NCE complications	P value
Frink, 2005 (21)	26 (31.3%)	57 (68.7%)	
Kawai,1998(20)	30 (75%)	10 (25%)	
Bickels,2002(19)	23 (20.9%)	87 (79.1%)	
Sum	79 (33.9%)	154 (66.1%)	.000(1)

Mann-Whitney U test

Table 3. Metasynthesis of the studies included – patellar complications

Study, year	Presence of post-NCE patellar complications	Absence of post-NCE patellar complications	P value
Frink, 2005(21)	1 (3.8%)	25 (96.2%)	
Kawai,1998(20)	2 (6.7%)	28 (93.3%)	
Schawb,2006(8)	35 (81.4%)	8 (18.6%)	
Sum	38 (38.4%)	61 (61.6 %)	.000(1)

(1) Mann-Whitney U test

which were sometimes scarcely precise and specific, and generally treated complications as secondary outcomes. The shortage of studies of better methodological quality was a barrier to our study. However, the findings that literature provides us on the subject came as a great surprise. We found several surveys with a low level of evidence (evidence level III or IV). 1-5,8,10,11,20,21,22-25 This reflects the challenge and the difficulty involved in clinical surveys on orthopedic oncology.

CONCLUSION

There is a need for the completion of studies focusing on the proposed topic, especially randomized clinical trials, in order to arrive at a more solid conclusion with respect to patellar replacement in patients with bone tumors in the knee. New surveys are necessary to reach conclusions on the proposed topic. In spite of the low methodological quality, rates of post-NCE complications can be considered high in international literature.

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