PROCESSING TIME OF LOANER ITEMS FOR TOTAL HIP REPLACEMENT

Intervalos de tempo para processamento de materiais consignados de prótese total de quadril

Intervalos de tiempo para el procesamiento de materiales consignados para prótesis total de cadera

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ABSTRACT: Objective: To estimate the time intervals necessary to reprocess loaner items for total hip replacement in a sterile processing department of a private hospital in São Paulo (SP). **Method:** This is an exploratory, descriptive field study with a quantitative approach. The sample consisted of 41 processing cycles for loaner items. Intervals were recorded using a digital stopwatch, including the start and end times of each activity. Sample calculation was estimated with a 95% confidence interval. **Results:** Median total processing time was 10 hours, total effective time was 4.9 hours, and the interval between the end of reprocessing and the time of surgery was 4.7 hours in advance. One surgery was canceled due to delayed delivery of the item. **Conclusions:** This study measured the reprocessing times of loaner items, maintaining the methodological rigor at all stages, with estimates that respected the confidence interval, making this investigation reproducible. We suggest that professionals from other facilities perform these measurements to allow the construction of indicators that can help nurses in decision-making.
Keywords: Time and motion studies. Hip prosthesis. Time perception. Perioperative nursing.

RESUMO: Objetivo: Estimar os intervalos de tempo envolvidos no reprocessamento de materiais consignados temporários de prótese total de quadril em um centro de material e esterilização de um hospital privado de São Paulo (SP). **Método:** Estudo exploratório-descritivo, de campo, com abordagem quantitativa. A amostra foi composta de 41 processamentos de materiais consignados. Os intervalos de tempo foram registrados com auxílio de cronômetro digital, hora inicial e final de cada atividade. O cálculo amostral foi estimado com intervalo de confiança de 95%. **Resultados:** O tempo total do processamento teve mediana de 10 horas, o tempo efetivo total foi de 4,9 horas e o intervalo de tempo entre o fim do reprocessamento e o horário da cirurgia foi de 4,7 horas de antecedência. Houve cancelamento de uma cirurgia em virtude do atraso na entrega do material. **Conclusão:** Nesta pesquisa foram mensurados os tempos de reprocessamento de materiais consignados, sendo mantido o rigor metodológico em todas as etapas, com estimativas que respeitaram o intervalo de confiança, o que faz deste estudo passível de reprodução. Sugere-se que profissionais de outras instituições realizem tais mensurações, de modo que permitam a construção de indicadores, auxiliando enfermeiros na tomada de decisão.
Palavras-chave: Estudos de tempo e movimento. Prótese de quadril. Percepção do tempo. Enfermagem perioperatória.

RESUMEN: Objetivo: Estimar los intervalos de tiempo involucrados en el reprocesamiento de materiales consignados temporalmente para reemplazo total de cadera en un Centro de Material y Esterilización de un hospital privado de São Paulo. **Método:** Estudio de campo exploratorio-descriptivo con enfoque cuantitativo. La muestra consistió en 41 procesamientos de materiales consignados. Los intervalos de tiempo se registraron con la ayuda de un cronómetro digital, hora de inicio y finalización de cada actividad. El cálculo del tamaño de la muestra se estimó con un intervalo de confianza del 95%. **Resultados:** El tiempo total de procesamiento tuvo una mediana de 10 horas; el tiempo efectivo total fue de 4,9 horas y el intervalo de tiempo entre el final del reprocesamiento y el momento de la cirugía fue de 4,7 horas antes. Se canceló una cirugía debido al retraso en la entrega del material. **Conclusión:** En esta investigación se midieron los tiempos de reprocesamiento de los materiales consignados, manteniendo el rigor metodológico en todas las etapas, con estimaciones que respetaron el intervalo de confianza, haciendo este estudio susceptible de reproducción. Se sugiere que profesionales de otras instituciones realicen dichas mediciones, de manera que permitan la construcción de indicadores, ayudando a las enfermeras en la toma de decisiones.
Palabras clave: Estudios de tiempo y movimiento. Prótesis de cadera. Percepción del tiempo. Enfermería perioperatoria.

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INTRODUCTION

In most facilities, dealing with loaner items is a daily struggle that can have strong negative effects on the productivity of the sterile processing department (SPD)[1].

Although Brazil does not have specific standards for managing loaner items, their processing is addressed in the Collegiate Board Resolution of the Brazilian Health Regulatory Agency (*Resolução da Diretoria Colegiada da Agência Nacional de Vigilância Sanitária* — RDC/Anvisa) no. 15/2012 on best practice requirements for processing healthcare products in the country[2]. The loan of surgical instruments is a common practice not only in Brazil but in many countries. Their high cost and the physical structure necessary to store these items make it impossible to maintain inventories. This logistics also involves some vendors that do not have an ideal inventory for distribution to all hospitals, with a high turnover in a short interval. As a result, this instrument is not always delivered with enough time for processing, directly affecting patient care, potentially risking the processing quality, and leading to delays or even suspensions of surgeries[3].

The loan process should consider the planning and provision of these items whenever they are requested by the medical teams during surgical scheduling. The main characteristic of loaner items is that they can be returned to vendors without any burden to the facility, paying source, or patient[4].

A critical item that needs to be loaned is the total hip replacement (THR) set, chosen for this study both for the complexity of its structural characteristic (cleaning difficulty, disassembly, access to residues, and the large number of boxes in a single surgery) and its increasing use. The number of THR surgeries has increased worldwide in the last decade due to demographic changes, including higher longevity, more sedentary lifestyle, and trauma (violence, car accidents)[5].

The lack or delayed provision of reprocessed loaner items for THR surgeries can directly impact the safety of patient care. This fact evidences the need for the development and execution of specific and well-designed processes and activities, ensuring that loaner items are sterile and complete at the time of surgery. SPD is responsible for determining the minimum time for item delivery so that reprocessing can be done in time for the surgery.

However, so far, no estimates have been made for the actual time intervals needed to process loaner items used in THR procedures.

OBJECTIVES

- To estimate the time interval necessary to reprocess loaner items for THR procedures in an SPD of a private hospital in São Paulo (SP);
- To estimate individual time intervals (in hours) for each stage involved in processing loaner items for THR, from receipt to the assembly of the surgery cart.

METHOD

This is an exploratory, descriptive field study with a quantitative approach. The feasibility of this research project was assessed by the Research Project Management System and the Research Ethics Committee of the facility under study.

Statisticians assisted the sample size calculation. The sample consisted of 41 processing cycles for THR loaner items. The processing time of loaner items for THR procedures was considered the dependent variable, while the complexity of the items (volume, weight, number of instruments, and boxes/baskets) was regarded as the independent variable.

Data collection had four steps:

1. Mapping all stages involved in the processing of loaner items for THR procedures;
2. Preparing and sending an invitation letter and informed consent form to judges and elaborating the instrument for validation;
3. Validation of the data collection instrument by selected judges with experience in the subject;
4. Data collection.

In order to reduce measurement bias and have better rigor/control and standardization, thus avoiding discrepancies among the examiners, data were collected exclusively by the first researcher. She contacted the department responsible for surgical scheduling daily to confirm the performance of elective surgeries in different shifts (morning, afternoon, and evening). The researcher arrived early at the site and directly observed the procedure, recording the initial time, the time spent on each activity, and the final time of the activities performed in the four reprocessing stages (receipt, cleaning, preparation, and sterilization) without influencing the processing. To that end, she used a digital stopwatch, pausing the timer if the processing was interrupted by any complication and starting it again when the activity was resumed.

All information was transcribed to a database. For data treatment and analysis, categorical variables were expressed as absolute frequencies and percentages, and numerical variables were described as mean and standard deviation (SD) or median and interquartile range, as well as minimum and maximum values. Estimates of total time intervals of the processing stages were presented as means followed by 95% confidence intervals (95%CI). Time interval estimates for idle items were expressed as medians followed by 95%CI. CIs for medians were calculated according to a method proposed in the literature[6]. Analyses were carried out using the SPSS software (SPSS Inc. Released 2008. SPSS Statistics for Windows, Version 17.0. Chicago: SPSS Inc.).

RESULTS

Advance delivery time

The advance time in which the six vendors delivered the items for processing in the facility was: 23 sets delivered 18 hours before surgery; 10 sets between 18 and 36 hours; 1 set between 37 and 47 hours; 4 sets between 48 and 71 hours; 3 sets over 72 hours.

Examples of non-compliance

Figure 1 illustrates some non-compliance aspects regarding the cleaning and damage of the items received.

Quantification of the items

Data from Table 1 show detailed descriptive analyses of information related to THR loaner items concerning: vendor, number of instruments, number of boxes, and number of baskets or trays.

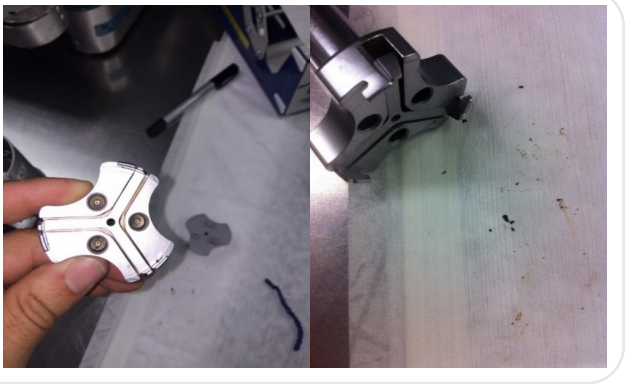

Figure 1. Item with residues received for total hip replacement surgery.

Total time intervals

Table 2 presents descriptive analyses of time intervals.

Item idle time

Table 3 brings descriptive analyses of idle time intervals.

Table 1. Vendor, number of instruments, and number of baskets or trays from the loaner sets for total hip replacement (n=41).

Vendor that delivered the item	n (%)
A	25 (61.0)
B	09 (22.0)
C	03 (7.3)
D	02 (4.9)
E	01 (2.4)
F	01 (2.4)
Total of instruments per processing cycle	
Median	150
(interquartile range)	(106–254)
Minimum–maximum	88–420
Number of boxes received	
Median	06
(interquartile range)	(4–12)
Minimum–maximum	4–19
Number of baskets or trays received	
Median	09
(interquartile range)	(6–17)
Minimum–maximum	6–24

Table 2. Total time intervals for each area involved in processing loaner items for total hip replacement (n=41).

Time at each stage	Median	IQR	Minimum–maximum
Receipt (minutes)	50	(34–91)	12–1,439
Cleaning (minutes)	85	(76–108)	73–405
Cleaning (hours)	1.4	(1.3–1.8)	1.2–6.8
Preparation (minutes)	135	(79–211)	46–693
Preparation (hours)	2.3	(1.3–3.5)	0.8–11.6
Sterilization (minutes)	131	(115–154)	79–340
Sterilization (hours)	2.2	(1.9–2.6)	1.3–5.7
Processing (minutes)	598	(505–730)	290–2,050
Processing (hours)	10.0	(8.4–12.2)	4.8–34.2

IQR: interquartile range.

Comparison of processing time by vendor

The median effective processing time was 291 minutes (or 4.9 hours). Table 4 shows detailed descriptive analyses of the effective time spent on the processing stages of loaner items evaluated with a stopwatch for companies A and B, responsible for 83% of the sample.

Table 3. Item idle time between the stages involved in processing loaner items for total hip replacement (n=41).

Item idle time (minutes)	Median	IQR	Minimum–maximum
Between receipt and cleaning	01	(0–13)	0–539
Between cleaning and preparation	16	(0–28)	0–241
Between preparation and sterilization	22	(1–59)	0–166
Between sterilization and time of surgery§	283	(159–625)	-150–963
Between sterilization and time of surgery (hours)§	4.7	(2.7–10.4)	-2.5–16.1

§Negative item idle times represent processing delays regarding the scheduled time of surgery (processing ended after the scheduled time of surgery); IQR: interquartile range.

Table 4. Effective time intervals for each stage involved in processing loaner items for total hip replacement for companies A and B*.

Effective time at each stage	Vendor	
	A (n=25)	B (n=9)
Receipt (minutes)	27.7 (12.3)	54.1 (17.2)
	10.1–53.1	35.7–86.9
Cleaning (minutes)	79.4 (10.9)	85.2 (8.7)
	72.3–125.2	76.0–100.5
Cleaning (hours)	1.3 (0.2)	1.4 (0.1)
	1.2–2.1	1.3–1.7
Preparation (minutes)	66.2 (20.1)	108.4 (26.8)
	39.6–135.0	60.9–140.5
Preparation (hours)	1.1 (0.3)	1.8 (0.4)
	0.7–2.3	1.0–2.3
Sterilization (minutes)	104.9 (18.0)	120.3 (17.4)
	71.8–142.8	99.7–151.1
Sterilization (hours)	1.7 (0.3)	2.0 (0.3)
	1.2–2.4	1.7–2.5
Processing (minutes)	278.3 (33.1)	368.1 (47.7)
	231.2–367.2	295.5–441.9
Processing (hours)	4.6 (0.6)	6.1 (0.8)
	3.9–6.1	4.9–7.4

*Values expressed as mean (standard deviation), minimum and maximum values.

DISCUSSION

Brazil has no definite recommendation for the minimum delivery time for loaner items to be timely processed. Nonetheless, Article 34 of Anvisa's RDC 15/2012 provides the following definition: "The professional in charge of the health service's SPD is responsible for: (...) III – Determining the time limit for the SPD to receive healthcare products that require processing before use and that do not belong to the health service" [2].

The International Association of Healthcare Central Service Materiel Management (IAHCSMM) recommends a two-day (48 hours) period before the time of surgery for known loaner boxes and three days (72 hours) for boxes processed for the first time[1]. In this study, the results showed that 56% of the 41 sets of loaner items were received by the facility less than 18 hours in advance of the scheduled time of surgery. Only 17% of the sample were delivered with an interval of over 48 hours and 7% over 72 hours. We underline that, in the last two cases, deliveries occurred on Fridays and on days that preceded holidays, with the surgical procedures scheduled for the next business day. Unfortunately, in the daily practice of hospitals worldwide, the delivery times pre-established by the facilities for loaner items are not always respected.

An article published in the journal of the Association of periOperative Registered Nurses demonstrates that this situation is experienced globally and not only in Brazil:

> Unfortunately, vendors frequently deliver loaner items to the health care facility just before the scheduled procedure; thus, loaner items may arrive at the user facility with insufficient time for them to be appropriately cleaned, inspected, inventoried, wrapped, sterilized, cooled, documented, and tracked to the patient according to published standards and recommended practices. This can result in staff members rushing to process the instrument trays, which often leads to missed steps or errors in reprocessing[7].

We highlight that RDC 15/2012 establishes that the facility is responsible for returning used loaner items clean[2].

However, aside from services that do not comply with this standard, Brazilian facilities show a large discrepancy regarding technological resources (automated washers versus manual cleaning).

Several non-compliance aspects were detected in the items delivered during this study, such as visible residues (Figure 1). These failures occur because, when loaner items are received, the concern is to check their type and quantity, while the cleaning quality is not often inspected.

Evidence of residues is often found during preparation, when the worker performs the cleaning inspection of the disassembled item with a magnifying glass and appropriate light. Another peculiarity of THR instrument loan sets that directly impacts their processing is the number of boxes and/or items that comprise them. The number of boxes in this study ranged from 4 to 19 for each THR set received (Table 1). We underline that each box had 1 to 3 baskets or trays that could be disassembled, that is, the boxes had different sizes. This diversity meant a variable number of trays in each box.

The median total processing time (Table 2) was 10 hours (approximately twice the effective time), considering the start of inspection until the item was ready for use. We emphasize that these values may change depending on the reality of each sector. By analyzing item idle times, we were able to identify when they occur, what the possible problems are, and correct them. Table 3 indicates that the longest idle time is between preparation and sterilization. This finding may be related to the loading of autoclaves to meet the daily demand. Table 3 also shows that the median interval between the end of processing and the scheduled surgery was 4.7 hours (not counting the total/effective processing time since the item was already available for use).

We highlight that two loan sets were ready after the scheduled time of surgery. In the first case, the processing ended two and a half hours after the schedule, and the surgery was canceled because there was not enough time to prepare the item, even though the company delivered it six hours before the scheduled time. The second loan set was delayed for 15 minutes, and the surgery was performed as planned.

The median effective processing time was 291 minutes (or 4.9 hours). Table 4 compared the effective time spent on each processing stage for companies A and B (83% of the sample), considering that their number of instruments and baskets is different, revealing that both companies affected these processing stages. This finding indicates important differences in the workload of professionals, in addition to increasing costs for the facility.

Challenges in the management of loaner items are a worldwide concern. Hospitals and official agencies in the United States and other countries have been discussing the issue in order to elaborate proposals for improvements and standardization of protocols. In Switzerland, documents relevant to the management of loaner items are often published by the Swiss Agency for Therapeutic Products (Swiss Medic)[8]. Australia has developed a guideline for the management of instrument loan sets, published by the state of Queensland[9], and also addresses the subject of loaner items in publications on the website of The Sterilizing Research and Advisory Council of Australia[10]. Besides the IAHCSMM, the World Health Organization also has recommendations for the management of loaner items, providing guidelines similar to those of the countries mentioned above[1,11]. Brazil is no different. Although we do not have specific standards for the management of loaner items, their processing is addressed in Anvisa's RDC 15/2012, which establishes best practice requirements for the processing of healthcare products[2].

Together with the legislation, these discussions serve as a foundation for safe practices, reducing the risks associated with failures in the management chain of these items and further strengthening the trust between hospital facilities and vendors of loaner items. This research sought to learn the processing time of THR loaner items. We found that this item is differentiated by weight, high load volume, and specificity regarding its compliance. These characteristics were crucial for better determining the minimum delivery time for vendors. We believe that these data can contribute to a safe practice, ensuring that the defined time interval does not overload the professionals processing the item, reducing the different risks for all parts that comprise the loan management chain and resulting in a safe practice both for the professionals involved and the patient undergoing surgical procedures.

CONCLUSION

This study fulfilled its objectives by measuring the processing time intervals of loaner items for THR procedures in the SPD of a private hospital in São Paulo. The median total processing time was 10 hours. The intervals varied for each processing stage, from the receipt to the assembly of the surgery cart. The median total effective time was 291 minutes (or 4.9 hours). We also described the effective time of each processing stage for companies A and B and the number of THR loaner items. Even if the processing time changes,

depending on the nature of the item, the methodological rigor maintained through all stages — with time estimates that respected the CI — makes this study reproducible. Thus, each SPD can identify their processing time intervals according to their reality. Of note, we found no other studies with similar objectives in the national and international literature.

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None.

CONFLICT OF INTERESTS

The authors declare there is no conflict of interests.

AUTHORS' CONTRIBUTION

GAAM: Conceptualization, Methodology, Project management, Supervision, Writing — review & editing. **TR:** Conceptualization, Investigation, Validation, Writing — original draft, Writing — review & editing.

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