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### **ORIGINAL**



# Protocol of major outpatient surgery in open cholecystectomy programmed in the service of general surgery of the Central Hospital of Maracay

Protocolo de cirugía mayor ambulatoria en colecistectomia abierta programadas en el servicio de cirugía general del Hospital Central de Maracay

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### **ABSTRACT**

**Introduction:** Major Outpatient Surgery (MOS) is a set of surgical, therapeutic, diagnostic procedures, as well as anesthetic techniques (local, locoregional, with or without sedation) that requires shorter postoperative care, which represents one of the most timely, economical and satisfactory changes for surgery.

**Objective:** was to evaluate a major outpatient surgery protocol in patients with scheduled open cholecystectomies in the general surgery service of the Central Hospital of Maracay in the period from January to August 2024.

**Method**: were a descriptive, observational, prospective, and longitudinal clinical-epidemiological study. The population consisted of 65 patients diagnosed with gallstones, with a sample of 37 selected. Statistical descriptions were performed, constructing 95 % confidence intervals for the variables.

**Results:** the average age was 47,78 years. The majority of patients were women. The absence of underlying medical history was evident. Of the 37 patients, 30 had satisfactory resolution of the pathology, without requiring readmissions, reoperations, or complications. Only 7 of the individuals presented minor complications, with effective resolution. The quality indicators for major outpatient surgery confirmed the effectiveness that the protocol can provide.

**Conclusions:** MOS is an innovative alternative that optimizes surgical care by allowing patients to return home the same day of the intervention, in addition to demonstrating a low rate of postoperative complications, giving satisfactory results in a short period of time, which is why its implementation is recommended.

**Keywords:** Outpatient Major Surgery; Open Cholecystectomies; Therapeutic Surgical Procedures; Quality Indicators.

## **RESUMEN**

Introducción: la Cirugía Mayor Ambulatoria (CMA) es un conjunto de procedimientos quirúrgicos, terapéuticos, diagnósticos, así como las técnicas anestésicas (local, loco regional, con o sin sedación) que requiere cuidados postoperatorios de menor duración, lo que representa uno de los cambios más oportunos, económicos y satisfactorios para la cirugía.

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**Objetivo:** evaluar un protocolo de cirugía mayor ambulatoria en los pacientes de colecistectomías abiertas programadas en el servicio de cirugía general del Hospital Central de Maracay en el período comprendido desde enero a agosto del 2024.

**Método:** se trata de una investigación clínico-epidemiológica de tipo descriptivo, observacional, prospectivo y longitudinal. La población consistió en 65 pacientes con diagnóstico de litiasis vesicular, seleccionando una muestra de 37 pacientes. Se realizó descripción estadística, construyendo intervalos de confianza al 95 % para las variables.

Resultados: destaca una edad promedio: 47,78 años. La mayoría de los pacientes eran mujeres. La ausencia de antecedentes de base fue evidenciable. De 37 pacientes, 30 de ellos tuvo resolución satisfactoria de la patología, sin ameritar reingresos, reintervenciones y sin complicaciones. Solo 7 de los individuos presentaron complicaciones menores, con resolución efectiva. Los indicadores de calidad de cirugía mayor ambulatoria constataron la efectividad que el protocolo puede brindar.

Conclusiones: la cirugía mayor ambulatoria es una innovadora alternativa que optimiza la atención quirúrgica al permitir a los pacientes regresar a sus hogares el mismo día de la intervención, además de evidenciar una baja tasa de complicaciones postoperatorias, dando resultados satisfactorios en un corto período de tiempo por lo cual se recomienda su implementación.

Palabras clave: Cirugía Mayor Ambulatoria; Colecistectomías Abiertas; Procedimientos Quirúrgicos Terapéuticos; Indicadores de Calidad.

#### INTRODUCTION

Major Outpatient Surgery does not represent a new model, being an exercise as old as surgery itself, since surgery emerged long before the invention of health centers or hospitals and, subsequently, was associated with them, which means that, since the creation of surgery, postoperative recovery was carried out at home. (1,2)

In the United States, approximately 22.5 million outpatient surgical interventions were recorded in 2017, of which only 2 % required hospitalization. Therefore, it represented an increase in the number of patients who used this modality, which is due not only to the improvement in anesthetic techniques, but also to the use of minimally invasive surgery.<sup>(3)</sup>

In Latin America, progress has been slower. In countries such as Chile, Colombia, and Guatemala, among others, scientific publications have been presented on various cases of laparoscopic surgeries (mainly cholecystectomies and hernioplasties), performed on an outpatient basis and others requiring hospitalization. These publications emphasize patient safety due to proper patient selection and the maintenance of quality service in an outpatient setting. Likewise, same-day discharge has prevailed, as has the absence of hospitalization for adequate postoperative care. (1-13)

On the other hand, Venezuela has little information on the CMA protocol, so it is rarely applied. It is almost exclusively used for the management of surgical pathologies within health centers belonging to the Barrio Adentro Mission, where there is an operating room and few hospitalization wards, where the patient is operated on and, after a period of observation, is discharged to recover outside the hospital at home. Given the limited publicity of the benefits provided by this modality, resistance on the part of surgeons, the lack of reliable support in the event of complications, and even the patient's preference to remain hospitalized at least one night, it is rarely applied in the national territory.<sup>(2,7,8,9)</sup>

The protocol for Outpatient Major Surgery consists of certain inclusion criteria, which take into consideration: the patient's chronic history, associated acute pathologies, the type of surgical intervention to be performed and the choice of surgical technique (which may be laparoscopic or not), which contains the least amount of transoperative complications and the appropriate anesthetic technique, which allows the prompt reversal of the anesthetic effects as well as the analgesic management of postoperative pain. (4,5)

It can be seen as a multidisciplinary model, reducing hospital stays, thus promoting a greater flow of patients with their respective surgical resolution, without using the scarce hospital beds, which is why it is also called "day surgery", "transitory hospitalization" or "23-hour surgery". Taking this into consideration, the establishments where this type of protocol is applied have units that require both structural and functional conditions, and resources that facilitate and guarantee efficient operation, keeping patient safety as their main objective. Likewise, the healthcare team is trained in a multidisciplinary manner to carry out this procedure. (1,2,4,5,6) Patient safety is the first quality of any Outpatient Surgery program and does not lie in the fact of being admitted to the hospital or not, but in an adequate patient selection and careful surgical and anesthetic practice. (3)

Major outpatient surgery is a complex management process involving multiple stakeholders throughout all phases. This process must be based on various general criteria that guarantee the quality of care. There are

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numerous indicators of quality of care in ambulatory care, many of which depend, like the quality criteria, on the structural and organizational characteristics of the ambulatory care unit. In any case, the quality indicators must consider the fundamental aspects of the unit's structure, efficiency and quality of care, internal functioning, morbidity, professional coordination, and perceived quality. And they are based on the six basic clinical indicators: cancellation of surgery, reoperation, unscheduled admission, unscheduled postoperative consultation, unscheduled readmission, and patient satisfaction.<sup>(3,14,15)</sup>

In this context, a study conducted in Spain determined that the application of the major outpatient surgery protocol in 3 051 patients who underwent surgery at that health center resulted in a 70 % rate of hospital discharges in less than 24 hours. Patients were discharged successfully without immediate postoperative complications, saving 2 112 hospital stays. (11) Similarly, the existing literature shows that this therapy is more cost-effective and safer than surgery with a long hospital stay when the guidelines and recommendations are strictly followed; and that, although the incidence of complications related to major outpatient surgery is very low, there are other clinical indicators that are specific, such as the readmission rate or the hospitalization rate, as well as establishing the parameters and criteria for inclusion in the major outpatient surgery protocol. (4) And that they can reach 69,2 % as a degree of satisfaction. Thus demonstrating the high rate of safety and efficacy of the Outpatient Major Surgery protocol and its few complications. (2)

Although major outpatient surgery became known in the 1990s, this surgical practice has been rarely used in Venezuela because it is a little-known surgical model. Although various research projects worldwide support the feasibility of implementing this protocol in any hospital, In the state of Aragua, specifically at the Maracay Central Hospital, no projects have been developed that consider major outpatient surgery as a protocol for open cholecystectomies. Therefore, the researchers set the general objective of evaluating a major outpatient surgery protocol for patients undergoing open cholecystectomies scheduled in the general surgery department of the Maracay Central Hospital from January to August 2024.

#### MFTHOD

This study was carried out as a descriptive, observational, prospective, longitudinal, and documentary clinical-epidemiological research. Previously approved and authorized by the respective Bioethics Committee, it was developed at the facilities of the General Surgery Service of the Autonomous Service of the Central Hospital of Maracay, Las Delicias Parish, Girardot Municipality, Maracay City, Aragua State, Venezuela, from January to August 2024. The population who underwent open cholecystectomy, under the scheduled surgery model, in the General Surgery Service of the Autonomous Service of the Central Hospital of Maracay, was 65 patients, whose simple sample was made up of 37 patients, who met the inclusion criteria according to the Outpatient Major Surgery protocol.

In order to avoid a range of random error, all patients diagnosed with gallstones who met the inclusion criteria were included in the study.

#### **RESULTS**

Among the epidemiological characteristics obtained after the evaluation of the sample, in the period of this study, the mean age was 47,78 years with a standard deviation of 12,79. Likewise, in the age group, the group comprised of ages 41 to 60 years of age predominated, that is, 43,24 %, followed by the age group of 20 to 40 years, which were expressed in 37,84 % and the lowest prevalence was the age group of 61 to 80 years, where it was represented by only 18,92 % of the population (table 1).

Regarding the predominant gender in the study, it was predominantly female, with a result of 86,49 %. Regarding the personal history of the patients studied, the group with the highest prevalence was those without diagnosed chronic pathologies , expressed at 62,16 %. High blood pressure was the most prevalent systemic noxa, representing 29,73 % of the results; followed by Diabetes Mellitus, where it was evident in 8,11 % of cases.

Likewise, the socioeconomic level, represented by strata, according to the Graffar scale, indicated that the predominant stratum accepted within the inclusion criteria was stratum III in 56,76 % of the population, while stratum II represented 32,43 %, and with a lower prevalence strata IV and I which barely represented 8,11 % and 2,70 %, respectively. It is important to emphasize that access to a health center close to home, expressed in two groups, the highest prevalence was found in those whose proximity was less than 5 kilometers, this being 94,59 %, while, the group that presented its proximity greater than 5 kilometers represented 5,41 % (table 1).

The CMA has been dedicated to carefully controlling the factors that directly influence this surgical model, which range from the choice of patient, the type of intervention to be performed, as well as associated pathologies and anesthetic considerations, which guarantee rapid satisfactory evolution and reduce the probability of presenting any postoperative complications, as well as the ability to identify and resolve in a timely manner any complications presented by the surgical intervention under the 23-hour surgery model (table 2).

Table 1. Socio-epidemiological characteristics and personal history of patients with major outpatient surgery scheduled in the General Surgery Service of the Autonomous Service of the Central Hospital of Maracay

Epidemiological data		n*	% н	95%CI <sup>1</sup>
Age (X + SD)	47,78 <u>+</u> 12,79			
Age (groups)	20 to 40 years	14	37,84	20,29 - 66,70
	41 to 60 years old	16	43,24	27,10 - 60,51
	61 to 80 years old	7	18,92	7,96 - 35,16
Sex	Female	32	86,49	71,23 - 95,46
	Male	5	13,51	4,54 - 28,77
Personal Background	None	23	62,16	44,76 - 77,54
	HBP	11	29,73	15,87 - 46,98
	DM2	3	8,11	1,70 - 21,91
Graffar Scale	Yo	1	2,70	0,07 - 14,16
	II	12	32,43	18,01 - 49,79
	III	21	56,76	39,49 - 72,90
	IV	3	8,11	1,70 - 21,91
Nearby health center	Less than 5 km	35	94,59	81,81 - 99,34
	Greater than 5 km	2	5,41	0,66 - 18,19
* F 0/11 B	. 050/61 050/6 6:1		1.6	1 1 1111

n\*: Frequency. %H: Percentage. 95%CI: 95% Confidence Interval for probability. HBP: High Blood Pressure. DM2: Type 2 Diabetes Mellitus.

To this end, four main items were evaluated, namely: a. Patient-specific characteristics, b. Physiological aspects of the patient, c. Psychosocial aspects, and d. Anesthetic criteria. These were applied to each patient to determine the possibility of surgical resolution in the selected sample, under the Outpatient Major Surgery model (table 2).

#### Table 2. Outpatient Major Surgery Protocol, adapted to the General Surgery Service of the Autonomous Teaching Service of the Central Hospital of Maracay Patients • Age 20 to 80 years characteristics Voluntary participation and informed consent of the patient. Cooperative patient and able to understand verbal and written orders. ASA I and ASA II. Ability to return home independently immediately after surgery. Easy access to a health center with surgical services. Access to postoperative treatment. Low risk of bleeding. Graffar stratum I, II, III and IV Physiological Severe obesity is considered a contraindication criterion greater than 30% of ideal weight. aspects Patients on anticoagulant treatment. Patient with a history of myopathies and neuropathies. Family history of myopathies and neuropathies. You must go with a responsible adult who will accompany you during the process. The patient must have a telephone for postoperative follow-up. Psychosocial aspects The patient and/or responsible adult must have the ability to understand in order to correctly execute the instructions and postoperative care at home. Previous Anesthetic Complication. Anesthetic criteria Complete recovery of consciousness or of the patient's previous condition. Ability to walk independently or with minimal assistance. Liquid tolerance. Spontaneous diuresis. Stable hemodynamics.

Type of Anesthesia (local, conductive, general less than 120 minutes).

Dependence on the use of illicit substances.

Asa I and II

Good Analgesia.

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When the major outpatient surgery protocol was applied to the previously selected patients, it was found that 100 % of the patients did not present any postoperative complications in the immediate postoperative period. Likewise, during the immediate postoperative period, the prevalence of patients without complications was 78,38 %; however, these adverse manifestations were evident in a minority of the sample: seroma in 18,9 %, and, to a lesser extent, superficial surgical site infection, representing 2,70 % of cases (table 3).

In the late postoperative evaluation, 94,59% of patients were free of complications. The lowest number of patients presenting these manifestations was superficial surgical site infection (2,70%), and wound dehiscence (2,70%). Finally, the presence of postoperative pain, assessed using the visual analogue scale (VAS), which was applied at the three postoperative stages (immediate, intermediate, and late), showed a prevalence of less than five, representing 100% of the sample studied (table 3).

Table 3. Application of the outpatient major surgery protocol and the appearance of				
complications and postoperative pain at three cut-off points, in patients with scheduled				
surgeries in the General Surgery Service of the Autonomous Service of the Central Hospital				
of Maracay				

Complications		n*	% н	95%CI <sup>1</sup>
POI 24 hours'	None	37	100	90,51 - 100
POM 3rd day"	Seroma	7	18,92	7,96 - 35,16
	Superficial SSI	1	2,70	0,07 - 14,16
	None	29	78,38	61,79 - 90,17
POT 7th day**	Superficial SSI	1	2,70	0,07 - 14,16
	Wound dehiscence	1	2,70	0,07 - 14,16
	None	35	94,59	81,81 - 99,34
Postoperative pain				
POI 24 hours'	EVA greater than 5	0	0,00	0,00
	EVA less than 5	37	100	90,51 - 100
POM 3rd day"	EVA greater than 5	0	0,00	0,00
	EVA less than 5	37	100	90,51 - 100
POT 7th day**	EVA greater than 5	0	0,00	0,00
	EVA less than 5	37	100	90,51 - 100

After implementing the Outpatient Major Surgery protocol, it was evaluated against the established quality criteria. The result was that, in patients selected according to inclusion criteria, the surgical cancellation rate was zero, as all procedures were performed. That is, the procedure was performed without institutional complications in 100 % of cases (table 4).

Similarly, it was observed that 97,30% of the patients who underwent surgery maintained a successful rate of no reintervention. Regarding unplanned admissions or prolonged hospital stays, the patients in this study did not require any of these options, demonstrating that 100% of this sample had a successful hospital discharge, without requiring readmission during the postoperative period (table 4).

However, it was evident that patients attended unscheduled postoperative appointments, representing 24,32 % of the sample. However, the remaining 75,68 % of the individuals studied waited for their scheduled appointment without incident. Considering the hospital readmission rate, 100 % of the patients studied did not require readmission during their postoperative period (table 4).

Finally, patient satisfaction is established as an evaluative quality indicator of the Outpatient Major Surgery protocol, where it was established that 100 % of patients were satisfied after the application of this surgical system (table 4).

**Table 4.** Effectiveness of the outpatient major surgery protocol, and its quality indicators, applied to patients with scheduled surgeries in the General Surgery Service of the Autonomous Service of the Central Hospital of Maracay.

Indicators		n*	% н	95%CI <sup>1</sup>
Surgery cancellation	Yes	0	0,00	0,00
	No	37	100	90,51 - 100
Reintervention	Yes	1	2,70	0,07 - 14,16

	No	36	97,30	85,84 - 99,93
Unforeseen income	Yes	0	0,00	0,00
	No	37	100	90,51 - 100
Unscheduled PC	Yes	9	24,32	11,77 - 41,20
consultation	No	28	75,68	58,80 - 88,23
Unplanned re-entry	Yes	0	0,00	0,00
	No	37	100	90,51 - 100
Patient satisfaction	Yes	37	100	90,51 - 100
	No	0	0,00	0,00
*- F 0/ H - D	-t 0F%CI   . C		L -+ OF 0/	and had by 21.26 at

n\*: Frequency. % H: Percentage. 95%CI : Confidence Interval at 95 % probability.

#### DISCUSSION

In a study carried out, the average age of the population that was admitted to apply the protocol of outpatient major surgery was 52,5 years.<sup>(9)</sup> Which presents similarity with this study, whose average age of approximately 47 years. Likewise, said study ratifies the significance with respect to the predominant gender, and which is associated with gynecological interventions.<sup>(10)</sup> However, in this investigation, even when the significance of the result was equal to the female sex, the figure is associated with cholecystectomies and is presented as a difference to be considered.

The major outpatient surgery protocol is more adapted to the requirements of first world hospitals.<sup>(5)</sup> And therefore does not coincide with the results of the present study. With respect to complications related to surgical site infection and seroma, there are studies that show a rate of 8,9 per 100.<sup>(8)</sup> This is compared with the results of this investigation, where in the development of the postoperative days, in the immediate postoperative period (first 24 hours), no complications were obtained, while in the mediate (3rd day) and late (7th day) postoperative periods, these clinical manifestations were also evident, only having seroma in 7 patients, with a resolution between the mediate and late postoperative periods; meanwhile, the only person who presented surgical site infection had surgical wound dehiscence in the late postoperative period, which had non-surgical resolution.

Major outpatient surgery is established as an example of innovation in surgical techniques, allowing selected patients, regardless of the type of anesthesia used, to attend the health center where the scheduled intervention will be performed and, after a short recovery period, be discharged from the hospital in the first few hours postoperatively; after direct and repeated follow-up, patients return home on the day of the intervention until acceptable discharge criteria are met, thus eliminating the need to occupy inpatient beds. (12) This was evident in this research, where the vast majority of patients had a satisfactory postoperative course, with a minimal rate of complications and without requiring hospital readmissions.

Finally, regarding quality indicators, recent research, regardless of the type of institution, indicates that ongoing evaluation is necessary because they are essential for monitoring and evaluating a variety of activities; therefore, they must be measured periodically and systematically recorded. They confirm that with continuous improvement, a decrease in cancellation rates and suspended surgeries is evident, whether for institutional or patient-related reasons. (13,14,15) Furthermore, complications reported during the postoperative period were, for the most part, minor. And the patient satisfaction measurement rate was significantly high, covering almost three-quarters of the total population. (2,16) This is related to this study, since the total effectiveness of outpatient major surgery was evidenced, adapted to the requirements of the Central Hospital of Maracay, it enhances the veracity of the study and allows to evaluate the possibilities of application in other pathologies, and even other health areas, whether other surgical services such as traumatology and orthopedics, neurosurgery, among others, always keeping in mind the well-being of the patient as the first place for decision-making.

#### **CONCLUSIONS**

Major outpatient surgery, which includes an increasing number of procedures and has revolutionized surgical practice, is an alternative to conventional inpatient surgical treatment. It has been an important factor in reducing hospital costs at the centers studied. This experience has benefited the neediest population and has been very well received at the hospitals.

Therefore, it is concluded that the application of this system as a standard protocol should be considered permanently, given that it is a practice that rarely presents serious complications. And, if minor complications do occur, they are resolved within the first 30 days, or less, after surgery. In the case of this study, the role of major outpatient surgery was appreciated as an innovative alternative that optimizes surgical care by allowing patients to return home on the same day of the procedure, in addition to demonstrating a low rate of postoperative complications and high patient satisfaction. This model suggests considerable potential for

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implementation in different areas of healthcare, always maintaining patient well-being as a priority.

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## **CONFLICT OF INTEREST**

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