

# RETROSPECTIVE AND SINGLE-CENTER STUDY WITH THE AIM OF PHARMAECONOMIC ANALYSIS IN PREGNANCY TERMINATIONS AT SAN GIULIANO HOSPITAL OF ASL NAPOLI 2 NORD.

■ Filoso Immacolata<sup>1</sup>, Iacolare Maria Rosaria.<sup>2</sup>, Monti Ida <sup>3</sup>, Tortora Attilio<sup>4</sup>, Contiello Claudio<sup>5</sup>, De Luca Assunta<sup>5</sup>, Scarano Anna <sup>5</sup>, Gerbi Giovanni<sup>6</sup>, Mignano Gaetano<sup>6</sup>, Falconio Lucio Marcello<sup>7</sup>

<sup>1</sup> Director of Hospital Pharmacy; <sup>2</sup> Pharmacist Manager involved in the procurement of Implantable Medical Devices;

<sup>3</sup> Pharmacist Manager involved in the procurement of Medicines and Pharmaceuticals; <sup>4</sup> Pharmacist with a scholarship;

<sup>5</sup> Professional Nurse ; <sup>6</sup> Healthcare Operator (OSS);

<sup>7</sup> Pharmacist Manager involved in the procurement of Medical Devices and Medical Supplies.

■ **KEYWORDS:** Abortion, Voluntary termination of pregnancy, Pharmacological abortion, DRG

## ABSTRACT

### Introduction:

Pregnancy termination (IG) is a widely practiced clinical procedure and can be therapeutic (IGT), pharmacological (IGF), or surgical (IGS). The analysis of total costs associated with different methods is useful to highlight advantages and disadvantages for the patient and to enable decision-makers to intervene in a precise manner on company policies supported by concrete data. The relevant legislation governing pregnancy termination is Law 194/78, with specific reference to voluntary termination, permitted within the first 90 days of gestation. This deadline can only be exceeded in special cases, such as severe risk to the mother or fetal malformation. The Law 194/78 aims to ensure that the process of voluntary termination (IVG) is guaranteed, and in this sense, family planning clinics serve as a reference service for many women and couples. The organization of IVG services must be such that there is enough professional figures to provide women with access to voluntary pregnancy termination. From the latest reports published by the Ministry, there is a noticeable decrease in voluntary pregnancy terminations, a trend also observed among foreign women. This is undoubtedly influenced by the increased use of emergency contraception – Levonorgestrel (morning-after pill) and Ulipristal acetate (5-day after pill). On the other hand, due to the more frequent use of pharmacological termination (using Mifepristone+Prostaglandins), there is an increased access to termination within the first 8 weeks of gestation, which represents the deadline for undergoing this variant of the procedure.

### Materials and Methods:

The study is retrospective and uncentered, with an evaluation of data from questionnaires administered to patients who underwent Pregnancy Terminations in the years 2020, 2021, and 2022 at San Giuliano Hospital in Giugliano in Campania (Na), which falls within the territory of the Local Health Authority Napoli 2 Nord.

From the analysis of the questionnaires, it is possible to reconstruct sensitive patient data, including place and date of birth, residence, domicile, age, origin, education level, as well as all clinical data related to the patient and pregnancy in general. Surgical pregnancy termination compared to pharmacological termination appears to be less common in all three periods considered. The pharmacological method involves taking an anti-progesterone hormone (Mifepristone) followed by an analogue of prostaglandins (Misoprostol).

From a cost analysis perspective, the starting point was the Diagnosis Related Group (DRG) of pharmacological and surgical pregnancy terminations in the Campania Region for each method considered.

### Results:

The laboratory tests which the patient must undergo in the preliminary phase are the same in all abortion (IG) procedures. In the surgical treatment, the patient is admitted to the day hospital, and under anaesthesia, the gestational sac is removed (an invasive procedure with associated risks). In the pharmacological procedure, the patient makes three hospital visits for the administration of two tablets with different active ingredients and at least one follow-up.

### Conclusions:

Although there is a minimal difference between two Diagnosis-Related Groups (DRGs), only 40 euros, the total expenditure is higher in the case of IGF, which prevails significantly in terms of the number of cases compared to IGC. On the other hand, the involvement of professional figures, technical and logistical infrastructure, is inconsistent in IGF, whereas it is much greater in the case of IGC. With IGF, the patient does not undergo any anaesthesia evaluation or surgical intervention, with recovery times estimated to be a few hours and, above all, exposing the patient to fewer risks than the surgical procedure. Additionally, medical and healthcare staff and the operating room structure with all intervention techniques are engaged to a lesser extent in IGF compared to IGC, generating potentially higher company marginality in IGF, especially considering the actual cost of the drugs used. It is worth noting that the DRG falls under regional jurisdiction and may not be the same across the entire national territory. In fact, the Campania Region's case may be different in other regions, resulting in a higher reimbursement amount for IGC treatment compared to IGF.

## INTRODUCTION

Pregnancy termination (IG) is a widely practiced clinical procedure and can be therapeutic (IGT), pharmacological (IGF), or surgical (ICG). The analysis of total costs related to these different methods is useful to highlight advantages and disadvantages for the patient and to allow decision makers to intervene precisely in company policies supported by concrete data.

In the two-year period of 2019-2020 in Italy, approximately 175,000 pregnancy terminations were performed, of which around 140,000 were voluntary terminations.

YEAR	2019	2020
N° IG	91508	85000
N° IVG	73207	66413

**Tab. 1:** *Number of Pregnancy Terminations in the years 2019 and 2020.*

The relevant Italian legislation that regulates pregnancy termination is Law 194/78, with particular reference to voluntary termination, which is allowed within the first 90 days of gestation. This deadline can only be exceeded in special cases, such as serious risk to the mother's health or fetal malformation.

The Italian Ministry of Health prepares an annual report to the Italian Parliament on the implementation of the law containing provisions for the protection of health (Law 194/78), using an epidemiological surveillance system for voluntary pregnancy terminations initiated in 1980. The data for this surveillance is provided by the National Institute of Health, Italian National Institute of Statistics (ISTAT), the Ministry of Health, Regions, and Autonomous Provinces. ISTAT provides the questionnaires administered and completed for each voluntary pregnancy termination in the facility where the procedure is performed. These questionnaires contain information on the socio-demographic characteristics of women, the services involved in issuing the document/certification, those performing the procedure, and the methods of execution. The Regions collect this information from the facilities that perform the pregnancy termination, analyze it to respond to quarterly questionnaires and an annual summary questionnaire (prepared by the National Institute of Health and the Ministry). These questionnaires include distributions for the modalities of each observed variable. The National Institute of Health ensures data quality control in constant contact with the Regions. Subsequently, in collaboration with ISTAT, it processes the tables presenting these distributions for each Region and for Italy.

Law 194/78 aims to ensure that the process of voluntary pregnancy termination is guaranteed, and in this regard, family planning clinics represent a reference service for many women and cou-

ples. The organization of pregnancy termination services must ensure a sufficient number of professionals to provide women with access to voluntary pregnancy termination, taking into account the high number of conscientious objectors in all health professional categories, particularly among gynecologists (64.6%).

According to the latest reports from the Ministry, there is a decrease in voluntary pregnancy terminations, which is also observed among foreign women, although they still have a higher risk of voluntary abortion compared to Italian women. Therefore, the need to promote informed and effective contraception for foreign women accessing the National Health Service, especially within the context of pregnancy care, remains confirmed.

Historically, the highest number of pregnancy terminations in Italy was recorded in 1983 with 234,801 cases. Generally, in recent years, there has been a constant decrease, and the abortion rate (number of pregnancy terminations per 1,000 women aged 15-49 residing in Italy) is among the lowest in Europe, as is the abortion ratio (number of pregnancy terminations per 1,000 live births). This decrease has undoubtedly been influenced by the increased use of emergency contraception – Levonorgestrel (morning-after pill) and Ulipristal acetate (5-day-after pill). On the other hand, probably due to the more frequent use of pharmacological abortion (with Mifepristone+Prostaglandins), there has been an increased access to termination within the first 8 weeks of gestation, which represents the deadline for pursuing this variant of the procedure.

## MATERIALS AND METHODS

The study is retrospective and single-center, involving the evaluation of data collected from questionnaires administered to patients who underwent Voluntary Pregnancy Termination in the years 2020, 2021, and 2022 at the San Giuliano Hospital in Giugliano in Campania (Na), which falls under the jurisdiction of the Local Health Authority Napoli 2 Nord.

Women seeking to undergo voluntary pregnancy termination within the structures of the Local Health Authority Napoli 2 Nord can access an integrated pathway between family planning centers and hospitals that have participated in the organizational program.

The patient's care is conducted according to a protocol aimed at exploring alternatives to Voluntary Pregnancy Termination (IGV). This process begins at the Family Planning Center (CF) of the patient's residential health district, where she will be received to ascertain and assess the motivations behind her choice and consider all possible alternatives to IGV (support from third-sector organizations, anonymous childbirth, etc.).

The gynecologist at the CF carries out health assessments (gestational age, general condition of

the pregnant woman) and, in a subsequent appointment, issues any necessary certification for the IGV procedure. After a seven-day interval, the case is reevaluated, and the pregnant woman is supported in her decision:

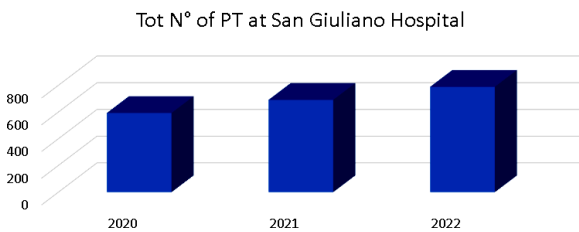
- In the event of reconsideration regarding IGV, the woman is taken under the care of the CF for pregnancy, childbirth, and post-partum support.

Simultaneously, the social worker at the CF facilitates connections with associations or reception facilities chosen by the woman for her chosen path.

In the case of a confirmed IGV, the CF gynecologist issues the woman a certificate confirming her pregnancy status and the request for termination. The gynecologist can then schedule the procedure at the company's hospital facilities, where the woman undergoes medical history and instrumental clinical exams. During this visit, an appointment for the IGV procedure in the Day Hospital is communicated to the woman.

The following personnel oversee the pathway: 1 Responsible Gynecologist, 1 midwife, 1 nurse, 1 cultural mediator (when necessary). Immediately after the procedure, the woman is invited to return to the referring CF, both for preventing future IGV occurrences and, if needed, for psychological support, and ultimately to promote conscious and responsible motherhood (contraception).

In the case of a minor, the consent of both parents or the legal guardian is required. However, when this is not possible for various reasons, authorization is granted by the guardian judge following a brief process of interviews, evaluation, and a report conducted by the gynecologist, psychologist, and social worker at the user's CF.



**Graph 1:** *Pregnancy Terminations in 2020 – 2021 – 2023 at San Giuliano Hospital*

From 2020 to 2022, the number of pregnancy terminations increased from 580 to around 800 in 2022. This absolute value indicates a notable increase in the phenomenon, counter to the national trend. The data may have been influenced by the restrictive measures during the Covid period, and the fact that approximately 60% of the requests for the procedure come from foreign women in absolute numbers.

Through the analysis of the questionnaires, it is possible to gather sensitive patient data such as place and date of birth, residence, domicile, age, educational background, as well as all clinical

data related to herself and the pregnancy in general.

PERCENTAGE OF PATIENT ORIGIN



- Italy ■ EU Countries ■ Non EU Countries

**Graph 2:** *Patient Origin in percentage*

Age is a significant factor; patients who underwent termination of pregnancy at P.O. San Giuliano between 2020 and 2022 with an age under 19 accounted for 46% of the total, while 37% were above the age of 20 and 17% were above the age of 40.

PERCENTAGE OF PATIENTS' AGE



- <19 years hold ■ >20 years hold ■ >40 years hold

**Graph 3:** *Patiens's Age in Percentage*

An interesting fact to highlight is that over 55% of non-Italian patients (around 60% of the total) who underwent the induced abortion were found to be under 19 years of age.

Another significant influencing factor for accessing this practice is the level of education. On average, only 12% of women seeking induced abortion have at least a bachelor's degree, while for 4%, their level of education couldn't be determined.

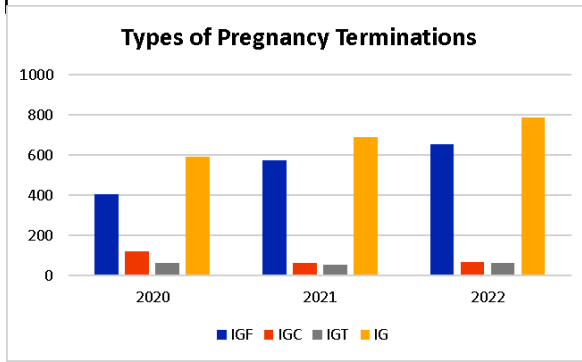
EDUCATIONAL LEVEL OF PATIENTS IN PERCENTAGE



- Elementary school ■ High school
- Middle school ■ Degree
- Not detectable

**Graph 4:** *Percentage of patients based on educational level*

Surgical abortion is less common compared to medical abortion in all three periods under consideration. The medical method involves taking an anti-progesterone hormone (Mifepristone) followed by a prostaglandin analog (Misoprostol).



**Graph 5:** Types of Pregnancy Terminations in 2020 - 2021 - 2023 at San Giuliano Hospital

The decrease in surgical interruptions in 2021 (64 cases) and 2022 (67 cases) is almost half compared to the 123 cases in 2020, which however are reabsorbed for the total by cases of drug interruptions in the respective years.

TERMINATION	2020	2021	2022
IGF	406	573	657
ICG	123	64	67

**Tab.2:** Decrease in the number of ICG cases compared to the increase in IGF cases in the years 2021 and 2022.

From a cost analysis perspective, we started with the Diagnosis-Related Group (DRG) for IGF and ICG in the Campania Region for each considered method.

TERMINATION	DRG Region Campania
IGF	€ 1080,00
ICG	€ 1040,00

**Tab.3:** Diagnosis Related Groups in Regione Campania in order to IGF and ICG

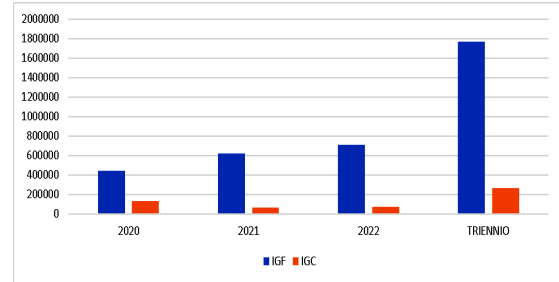
### RESULTS

The laboratory tests that the patient undergoes in the preliminary phase are the same for all abortion procedures. In the surgical treatment, the patient is hospitalized in day hospital and under anesthesia, the gestational sac is removed (an invasive procedure with associated risks). On the other hand, in the pharmacological method, the patient makes three hospital visits for the administration of two tablets with different active ingredients and at least one follow-up, which can also be three visits at 15, 30, and 60 days after the pharmacological administration.

The cost of the tablets is 60.05 euros for the first one (Mifepristone) and 16.30 euros for the second

one (Misoprostol = prostaglandin), which must be taken 2 days after the progesterone anti-hormone. The administration of prostaglandin can cause abdominal pain due to contractions, which is why at least one final outpatient check is performed after 15 days.

In absolute terms, the total cost over the 36 months for the surgical procedure was 454,480 euros, while for the pharmacological procedure it was 1,766,880 euros. This trend is consistent when analyzing individual years studied.



**Graph 6:** Expenses considering DRG for IGF and ICG in the Campania Region in the years 2020 – 2021 – 2023 and over the three-year period at the San Giuliano Hospital.

### CONCLUSIONS

Although there is a minimal difference of only 40 euros between the two DRGs, the expenses are higher in the case of IGF, which also prevail significantly in terms of the number of cases compared to ICG.

On the other hand, the involvement of professional figures, technical and logistical infrastructures, appears to be inconsistent in the cases of IGF and much greater in the case of ICG. With IGF, the patient does not undergo any anesthesiological investigation or surgical procedure, with recovery times estimated in a few hours, and especially with lower risks compared to the surgical procedure. Furthermore, the medical and healthcare staff and the operating room structure with all interventional methods are engaged to a lesser extent in IGF cases compared to ICG, potentially generating a higher marginal benefit for the organization in IGF cases, especially considering the actual cost of the drugs used.

From the patient's perspective, the administration of two or three tablets has a very different psychological and recovery impact compared to what can be considered a full-fledged surgical intervention. In a territory with a high rate of foreign residents, including non-European immigrants, and with a medium level of education among its residents in terms of achieved degrees, it is natural that the

	ALABORATORY Analysis	ANESTHESIOLOGICAL Consultation	OTHER INVOLVED INFRASTRUCTURES	OTHER INVOLVED LOGISTICAL INFRASTRUCTURES	OTHER INVOLVED PROFESSIONAL FIGURES
IGF	YES	NO	NO	NO	NO
ICG	YES	YES	YES	YES	YES

**Tab.4:** Different complexity between IGF e ICG

number of abortions in absolute value may be higher than the national average. It is worth noting that DRG is under regional jurisdiction and may not be the same throughout the national territory. It is possible that the Campania

case may be overturned in other regions, leading to a higher reimbursement amount for IGF treatment compared to IGC.

## REFERENCE

1. Spinelli A, Boccuzzo G, Grandolfo ME, Buratta V, Pediconi M, Donati S, Frova L, Timperi F. *Ann Ist Super Sanita. Evolution of voluntary interruption of pregnancy in Italy from its legalization until today.* 1999;35(2):307-14. PMID: 10645666 Italian.
2. Pignotti MS. *Recenti Prog Med. The Italian law on termination of pregnancy (194/1978). Should it be revised? The palliative care option.* 2007 Dec;98(12):607-10. PMID: 18369034 Italian.
3. Schwarzenberg TL, Canibus R, D'Agostino EM, Cavalli P, Acconcia P, Ciocca M, Giordano A. *Minerva Pediatr Induced abortion in adolescents.* 1987 Dec 31;39(23-24):1117. PMID: 3451066 Italian. No abstract available.
4. Bastianelli C, Lucantoni V, Papale S, Farris M, Niccoli VS, Subrizi DA, Primiero FM. *Contraception and voluntary termination of pregnancy. Survey of a sample of 500 women.* *Minerva Ginecol.* 1996 Sep;48(9):359-63. PMID: 8999383 Italian.
5. Marzi MM, Gottardi G, Spreafico A, La Vecchia C, Franceschi S, Riva A. *Ann Ostet Ginecol Med Perinat. Law 194 on voluntary abortion.* 1979 Jul-Aug;100(4):284-5. PMID: 554514 Italian.
6. Ricci G, Guidoni CG, Danero S, La Rosa R, Urbani T, Massone M, Mazzini M, Ambrosini A. *Patol Clin Ostet Ginecol. Radioimmunologic assay of PRL, E2 and prosterone, before and after pregnancy termination by metergoline and sulphiride.* 1983 May-Jun;11(3):213-8. PMID: 12266269 Italian.
7. Venuti FS, Granese D, Fattori A. *Rass Med Sper. Influence of some anesthesiologic methods on blood loss in procedures for voluntary termination of pregnancy.* 1980 Mar;27(3):191-8. PMID: 12279128 Italian.
8. Papini P, Rosano A, Schifano P, Cesaroni G, Di Lena P. *Epidemiol Prev. The relationship between the methods for performing voluntary pregnancy interruption and the sociodemographic characteristics of the women: the differences between Italian and non-EEC women in Rome, 1987-1993.* 1996 Apr-Sep;20(2-3):115-8. PMID: 8766293 Italian.
9. Sabbioni D. *Minerva Ginecol. Exceptional indications for the therapeutic interruption of pregnancy; very serious and total spondylolisthesis of the fifth lumbar vertebra.* 1956 Mar 15;8(5):236-8. PMID: 13333942 Italian.
10. Spinelli A, Grandolfo M, Pediconi M, Medda E, Talamanca IF. *Epidemiol Prev. The epidemiology of voluntary abortion in Italy.* 1991 Sep-Dec;13(48-49):198-200. PMID: 1843316 Italian.