

## BACKGROUND AND OBJECTIVE

Surgical bleeding, particularly uncontrolled bleeding, remains one of the most important complications of surgery. It presents a significant clinical and economic burden by increasing the risk of complications and mortality, which leads to a greater use of health resources (1). Therefore, the use of measures to achieve rapid hemostasis during surgery is essential to minimize complications and associated costs (2,3).

The aim of this study is to estimate the budget impact (BI) on the Spanish National Health System (SNHS) after introducing a novel sealant to stop bleeding during surgery, based on a combination of human fibrinogen and human thrombin (HF/HT), Veraseal™.

## METHODS

A BI analysis was carried out from the SNHS perspective, with a 3-year time horizon. Two scenarios were compared: before and after the introduction of HF/HT. Considering the history of procedures performed in the SNHS (2016 to 2018) (4), the number of surgeries for the next three years by surgical groups (cardiovascular, colorectal, hepatic and general surgeries) was estimated using a simple linear regression (Figure 1).

Subsequently, fibrinogen-containing solutions for sealant (FS) units sold for the next three years were estimated through a simple linear regression, considering the historic sales data from 2016 to 2019 (3). Table 1 shows the percentage of hemostatic treatment with FS per type of surgery for the years 2021, 2022 and 2023. It was considered that the 10 ml presentation is used for cardiovascular (5) and hepatic surgeries (6), and the 4 ml presentation is used for colorectal (7) and general surgeries (8–14).

Figure 1: Procedures performed in the SNHS (2016-2018)

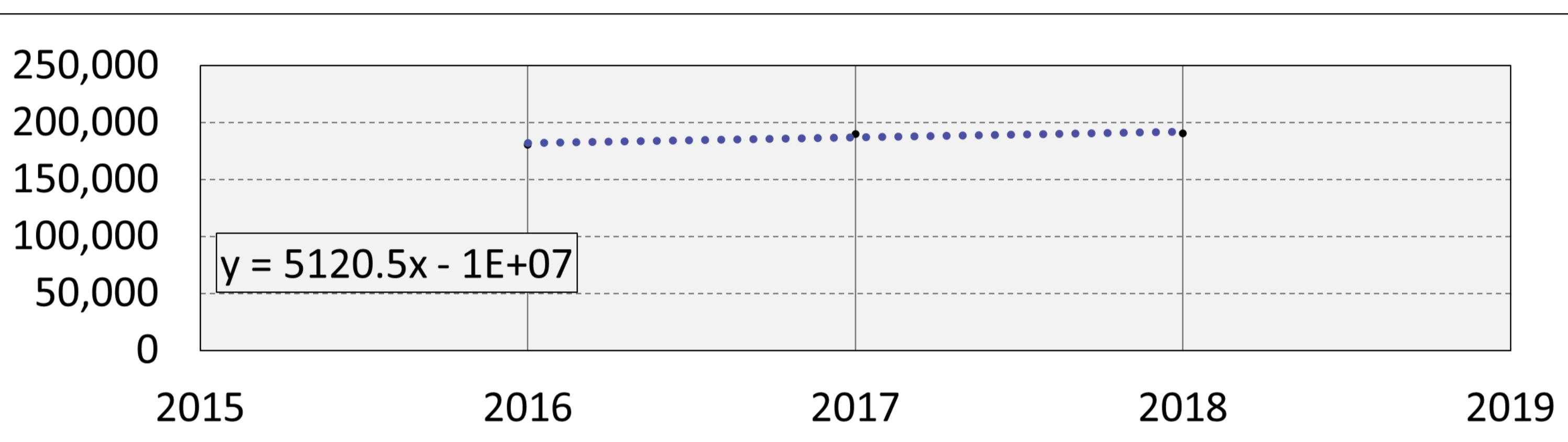


Table 1: Percentage of hemostatic treatment with FS

Type of surgery	2021	2022	2023
Cardiovascular and hepatic	16.92%	16.99%	17.05%
Colorectal and general	27.29%	29.45%	31.58%

Table 2: Mean units (ml) needed by type of surgery

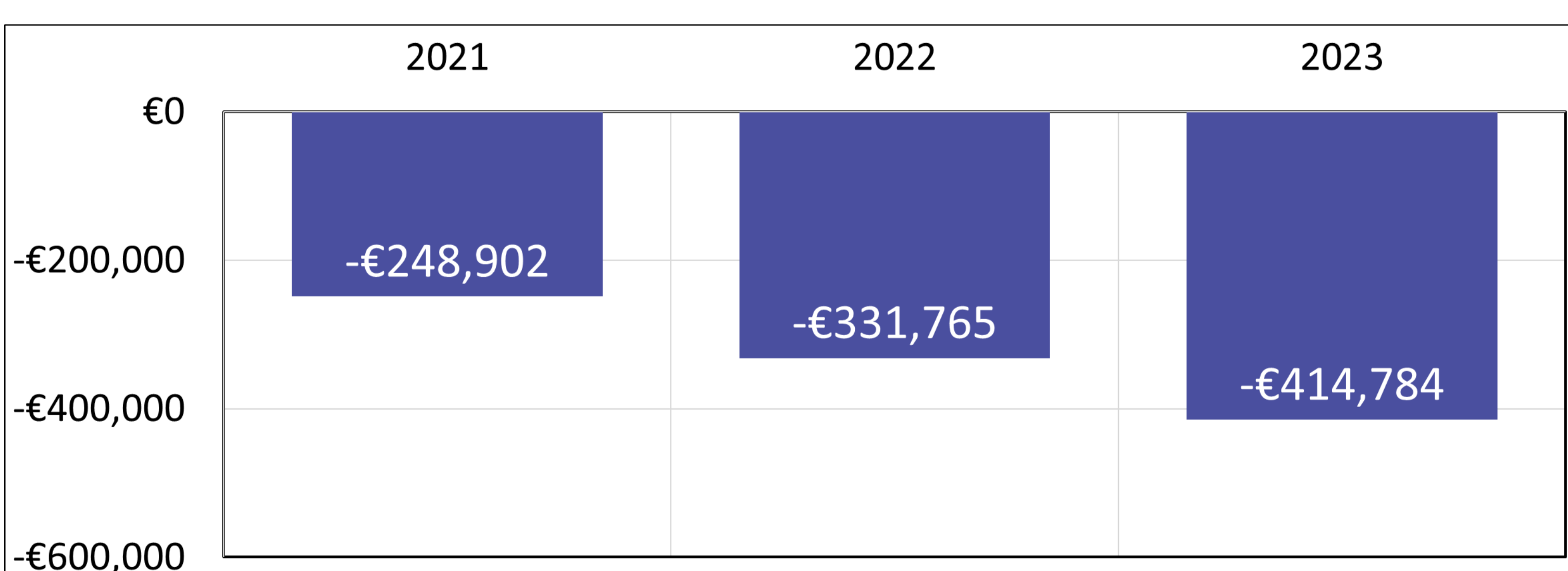
Type of surgery	HT/HF	Source	FS	Source
Cardiovascular	4.37 ml	(15,16)	5.40 ml	(5)
Colorectal	1.69 ml	(5–7,15–17)	2.00 ml	(7)
General	2.77 ml	(5,6,8–17)	3.28 ml	(8–14)
Hepatic	8.30 ml	(17)	9.40 ml	(6)

- ✓ The therapeutic alternatives evaluated were HF/HT and FS (incumbent comparator).
- ✓ A progressive introduction of HT/HF in the market was considered (11.02%, 13.66% and 15.95% for each year of the study, respectively).
- ✓ In the base case, no vial sharing has been considered.
- ✓ To calculate the average cost per procedure, the average doses of FS and HT/HF have been estimated by type of surgery (Table 2).
- ✓ The list price, the applicable discount by law of 7.5% (18) and the VAT (4%) were considered for drug costs.
  - List price HT/HF: €287 (4ml); €428 (10ml) (19)
  - List price FS: €273.28 (4ml); €605.15 (10 ml) (19)
- ✓ The robustness of the model was evaluated by a deterministic sensitivity analysis (DSA), varying the list price (-43,1%), the vial sharing (no wastage), and both, at the same time.

## RESULTS

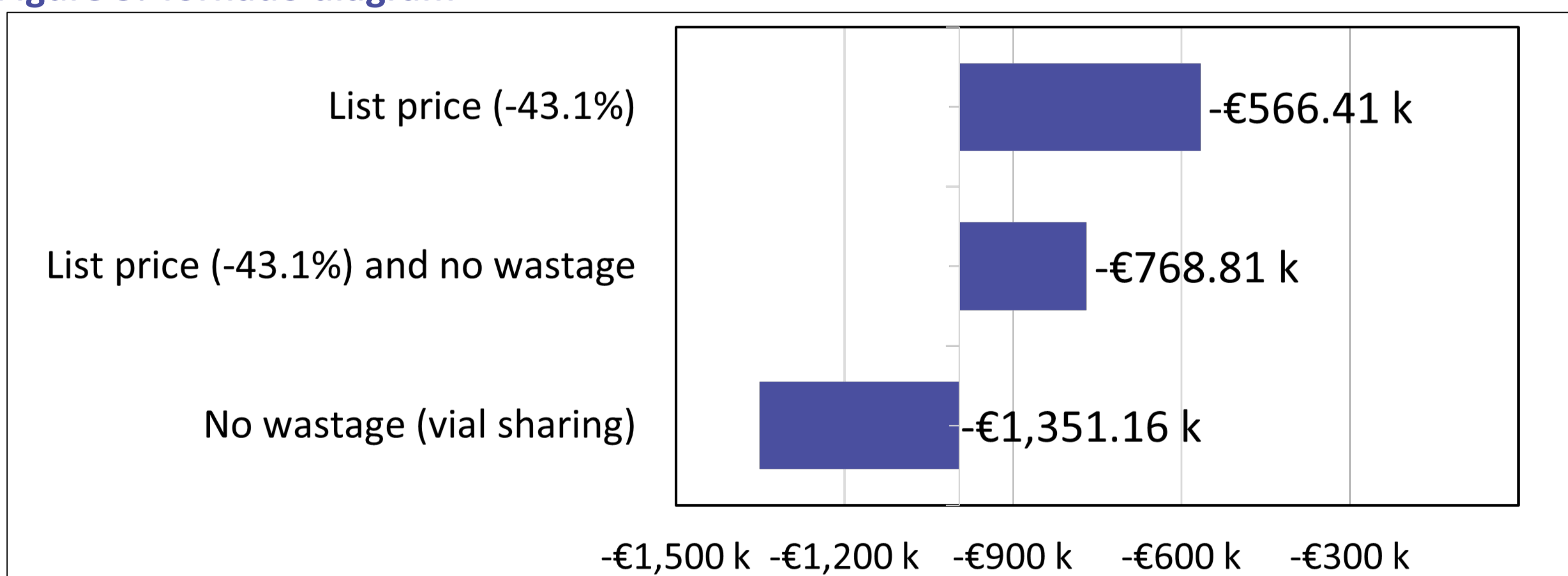
- ✓ The target surgical procedures potentially eligible for treatment with HF/HT are estimated at 47,636, 51,252, and 54,869 for each year of analysis, respectively.
- ✓ In the current scenario, the annual cost was €17,239,335, €18,447,669 and €19.656.002 for each year, respectively; and in the alternative scenario was €16,990,433, €18,115,904 and €19,241,218 for each year, respectively.
- ✓ The result shows that treatment with HF/HT is cost saving for the SNHS (Figure 2). The progressive introduction of HF/HT could generate savings at SNHS level of €248,902, €331,765 and €414,784 in the first, second and third year, respectively. The cumulative BI for the three years of analysis amounts to -€995,451.

Figure 2: Budget impact model results (by year)



- ✓ Figure 3 shows the DSA results. The DSA confirmed the robustness of the model and indicate that savings could be increased by 36% when including the vial sharing (no wastage). Reducing the list price produced savings of €566.412 in three years.

Figure 3: Tornado diagram



## CONCLUSIONS

The introduction of HT/HF for supportive care in adults when standard surgical techniques are insufficient to achieve hemostasis is associated with savings for the SNHS of €248,902, €331,765 and €414,784, respectively, for each year of analysis, leading to a cumulative BI of -€995,451 in three years. The DSA demonstrate sustained savings over the three years, which can increase by up to 36%.

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