

# OPEN PROSPECTIVE AND RANDOMIZED STUDY COMPARING THORACIC OR HUMERAL IMPLANTATION OF CENTRAL VENOUS ACCESS IN PATIENTS WITH SOLID TUMORS REQUIRING INTRAVENOUS CHEMOTHERAPY

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## INTRODUCTION

Implantable venous access device (Port-a-Cath = PAC) are subcutaneous systems used for the administration of intravenous anticancer treatments, minimizing extravasation risks. Usually, in our center, anesthesiologist have placed them in thoracic locations.

However, in recent years, radiologists have increasingly performed humeral placements. Retrospective studies showed no significant differences in complications (1,2).

**This prospective study aims to demonstrate the non-inferiority of humeral placement compared to thoracic location.**

## METHODS

This is a french phase IV prospective non-blinded, monocentric study. After randomization, patients were assigned to received thoracic or humeral PAC (ratio of 3:1). Patients presenting with localized or metastatic disease with minimal risks and constraints were included.

**The primary outcome was complications (hematoma, thrombosis, infection...) related to PAC within 12 months of implantation.** Second outcomes included patient satisfaction (visual analog scale) and the cost-effectiveness ratio (PAC installation and removing).

Table : Safety data upon 12 months

	Humeral Port-A-Cath (N=65)	Thoracic Port-A-Cath (N=213)	p-value (Fisher's exact test)
Patients who experienced at least one complication within 12 months	19 (29%)	26 (12%)	0.002
Patients who experienced at least one complication of grade CTCAE $\geq$ 2 within 12 months	7 (11%)	13 (6%)	0.272
Missing data	0	3	--
Patients who underwent at least one hospitalization (due to a complication) within 12 months	3 (5%)	8 (4%)	0.723
Maximum CTCAE grade per patient	--	--	< 0.001
1	12 (18%)	10 (5%)	--
2	1 (2%)	8 (4%)	--
3	6 (9%)	3 (1%)	--
4	0	2 (1%)	--
5	0	0	--
Missing data	0	3	--

## REFERENCES

1. Goltz JP et al. Identification of risk factors for catheter-related thrombosis in patients with totally implantable venous access ports in the forearm. J Vasc Access. 2012.
2. Wildgruber M et al. Short-term and long-term outcome of radiological-guided insertion of central venous access port devices implanted at the forearm: a retrospective monocenter analysis in 1704 patients. EurRadiol. 2015



## RESULTS

In the intention-to-treat analysis, 278 patients were randomized (65 humeral, 213 thoracic).

No significant differences were observed in baseline characteristics, types of chemotherapy, or cycles received. Complications within 12 months are presented in the table. **The difference complications between the two groups was estimated at 17% (90% CI: [7%; 27%]), which exceeds the non-inferiority margin set a priori at 3.5%.** Patient satisfaction score was higher in thoracic group (8,10 versus 7,25 ; p = 0.027). The mean cost of humeral PAC was 585€ versus 501€ for thoracic PAC, the Incremental cost-effectiveness ratio was 494 (IC 95% [219, 1520]).

## CONCLUSION

**The study failed to demonstrate the non inferiority of humeral PAC implantation.**

Due to low recruitment and unfavorable interim analysis results for the humeral PAC in clinical (higher complications), satisfaction (lower) and medical-economic dimensions (higher cost), the study was stopped prematurely.

However, some bias identified : difference for minor complications and single center. The final analysis with all patients (n = 361) is planned for January 2025. A multicenter study would be necessary to confirm these results.