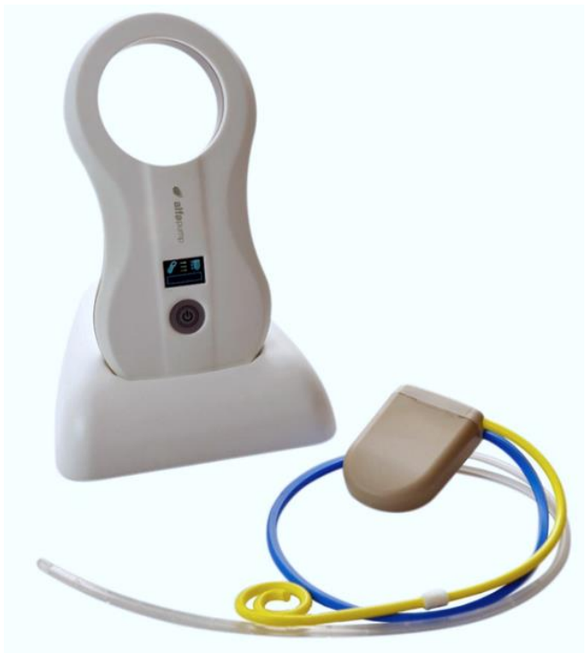

CONTINUOUS LOW-FLOW ASCITES DRAINAGE THROUGH THE URINARY BLADDER VIA THE ALFA-PUMP (AP) CLOSED SYSTEM IN PALLIATIVE PATIENTS WITH MALIGNANT ASCITES

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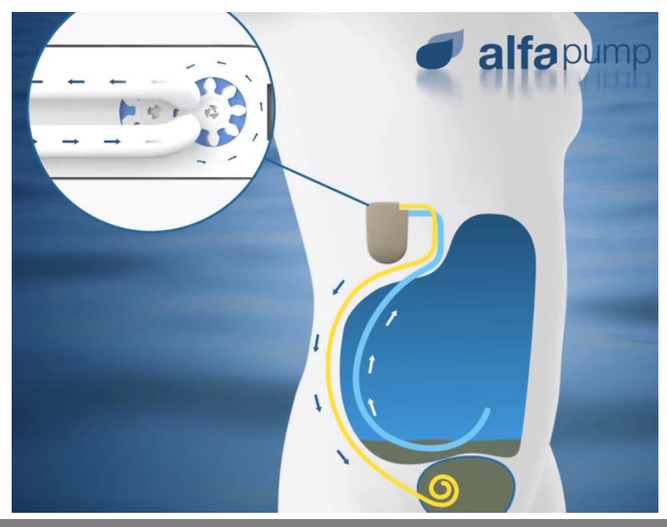
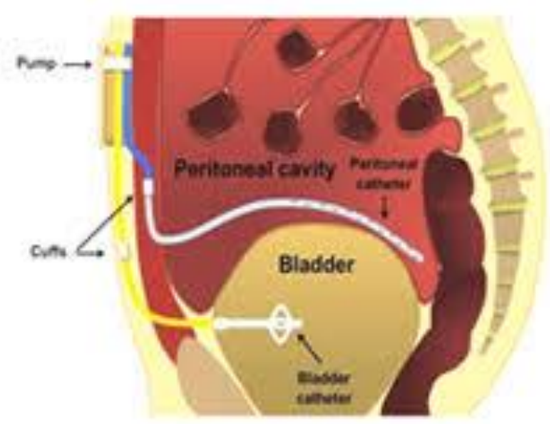
Aim

Malignant Ascites (MA) is a therapeutic dilemma significantly impairing patients' quality of life (QoL). The Sequana Medical AP-System, a subcutaneous, externally rechargeable, implantable device, draining ascites via the urinary bladder, is an established treatment in liver cirrhosis, but not in MA. We evaluated the AP-system in cancer patients with MA.

Methodology

We performed a retrospective multicentre evaluation of all consecutive patients who received an AP for MA-palliation in 6 centres across 3 European countries. AP was evaluated for its ability to pump MA and cross correlated with survival, symptom and retrospective physician-reported QoL.





Results

Seventeen eligible patients (70.6% female) across 13 different tumour types, the most common being ovarian cancer (48%), were analysed; median patient age: 63 y (N=17; range: 18-81). Median rate of paracenteses prior to AP-implantation was 1.39/month (n=14; range: 0.13-4.12); median ascitic volume (AV) was 6.8 L/month (n=10; range: 1.8-21.0). Median duration of AP-implantation was 60 minutes (N=17; range: 30-270) and median post-implantation length of stay of 4 days (N=17; range: 2-24). 12 protocol-defined AE occurred in 8 patients: 4 renal failures, 4 pump-/catheter blockages, 3 infections/peritonitis and 1 wound dehiscence. Median AV pumped daily was 303.6 mL/day (range: 5.6-989.3) and median total AV drained was 28 L (range: 1-638.6). Median patient post-AP-survival: 89 days (n=15; range: 10-715) and 16 patients had the pump in situ at death. Four patients needed 1 single post-implant paracentesis; a 5th patient required LVP but the number of LVP events was not reported. Eleven patients received anticancer treatment after AP-implantation. In a physician-reported QoL questionnaire, 71% experienced an improvement post AP-implantation of at least one of following QoL parameters: tiredness, pain & bloating, sleeping, shortness of breath, appetite and nutritional-status.

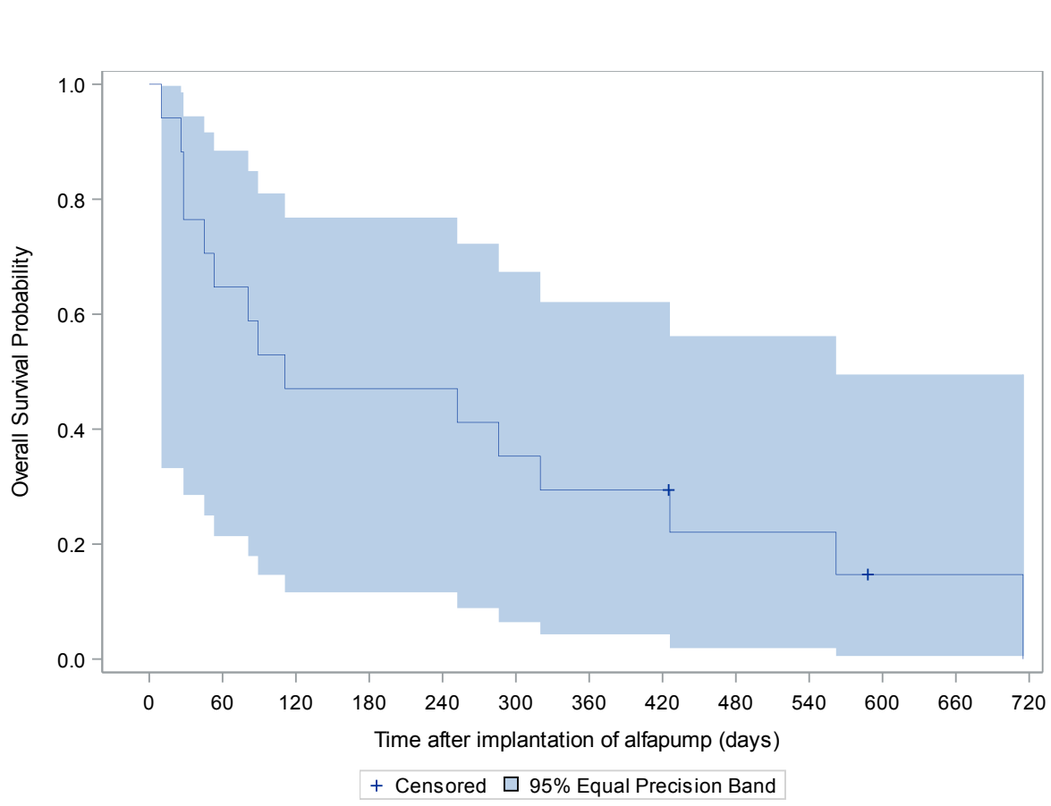


Figure 1. *Patient Survival Kaplan-Meier*

	N	Median [Q1, Q3]	Mean ± SD	Min, Max
Prior to Implant				
Paracentesis				
Event Rate[1] (# Events/Months*)	14	1.39 [0.64, 2.43]	1.64 ± 1.19	0.13, 4.13
Volume Rate[2] (Liters/Months)	10	6.78 [3.00, 11.41]	7.89 ± 6.03	1.80, 21.00
LVP				
Event Rate[1] (# Events/Months)	13	0.00 [0.00, 1.06]	0.65 ± 1.00	0.00, 3.00
Volume Rate[2] (Liters/Months)	6	8.48 [4.28, 11.34]	9.26 ± 6.83	2.45, 21.00
Post Implant				
Paracentesis				
Event Rate[1] (# Events/Months)	8	0.04 [0.00, 0.21]	0.24 ± 0.42	0.00, 1.15
Volume Rate[2] (Liters/Months)	3	0.81 [0.54, 0.97]	0.74 ± 0.43	0.28, 1.13
LVP				
Event Rate[1] (# Events/Months)	1	NA[3]	NA	NA
Volume Rate[2] (Liters/Months)	0	NA[3]	NA	NA

[1]Including patients who had known zero events. [2]Excluding patients who had known zero events and therefore zero volume.. 3 No event numbers nor volume data recorded for patient who required LVP therefore no volume nor event rates calculable. *Month = 30 Days

Table 1. *Comparison of Pre and Post-implant Paracentesis and LVP – Events and Volumes per Patient*
LVP: large volume paracentesis

Conclusion

AP appears to be effective in palliating patients with MA and improving their QoL. Its broader implementation in oncology services should be explored.

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