

ERN eUROGEN registry

Report on Expertise Area 2.1

INTRODUCTION

This report entails an analysis of the data on Expertise Area 2.1: Complicated and complex pelvic floor disorders: AMS800 in the ERN eUROGEN registry. This report aims to give insight in the current clinical practices using the Clinical Practice Snapshot data about the patients entered. As patient numbers are not similar across HCPs, the results cannot be equally compared between HCPs, but the analyses give an indication of trends.

Please keep in mind that these reports are meant to inform you about some general treatment characteristics using the Clinical Practice Snapshot data, not to perform in-depth statistical analyses. If you have any suggestions about information to add to these reports, or to delete because the information is not relevant, please let us know and it will be considered for the next report.

EA 2.1; COMPLICATED AND COMPLEX PELVIC FLOOR DISORDERS: AMS800

Descriptive statistics

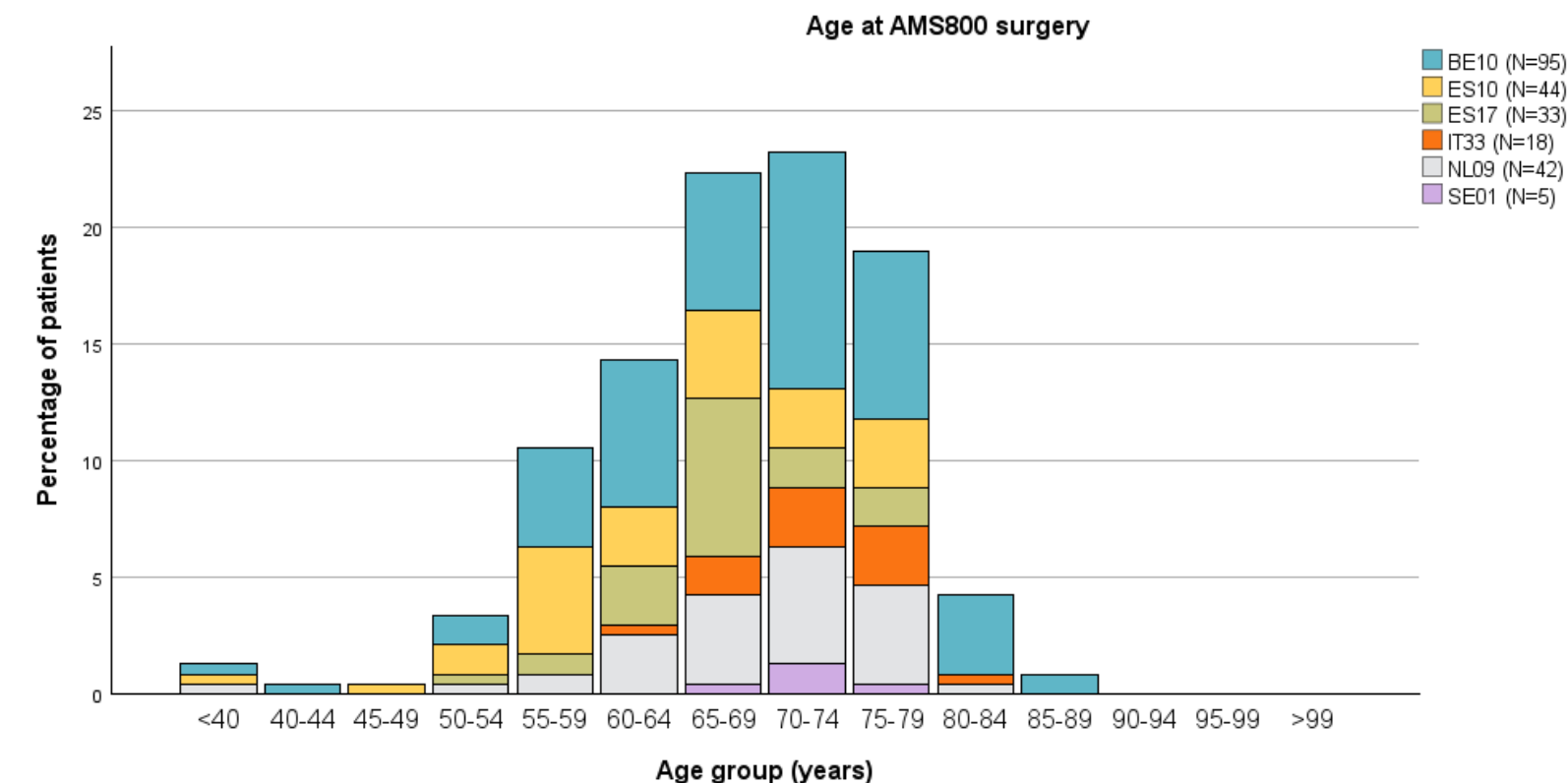
The table below provides an overview of the descriptive statistics for patients from Expertise Area 2.1, complicated and complex pelvic floor disorders treated with an AMS800 device. Corresponding figures were made of the variables, and they are displayed on the next pages.

	Total N=238	Belgium BE10 (N=95)	Spain		Italy IT33 (N=19)	Netherlands NL09 (N=42)	Sweden SE01 (N=5)
			ES10 (N=44)	ES17 (N=33)			
AMS800 implant surgery							
Age at 1 st surgery; Median (range)	69 years (17;88)	71 years (35;88)	65 years (17;79)	68 years (54;77)	74 years (64;81)	70 years (25;83)	72 years (69;77)
Activation of AMS800 device							
Within 6 weeks; N (%)	192 (80.7%)	88 (92.6%)	38 (86.4%)	5 (15.2%)	17 (89.5%)	40 (95.2%)	4 (80.0%)
Later; N (%)	38 (16.0%)	4 (4.2%)	1 (2.3%)	28 (84.8%)	2 (10.5%)	2 (4.8%)	1 (20.0%)
No activation in 1st yr of trt*; N (%)	7 (2.9%)	3 (3.2%)	4 (9.1%)	-	-	-	-
Unknown: N (%)	1 (0.4%)	-	1 (2.3%)	-	-	-	-
Complications after surgery							
Within 6 weeks							
No complications; N (%)	193 (81.1%)	83 (87.4%)	37 (83.7%)	29 (87.9%)	16 (84.2%)	24 (57.1%)	4 (80.0%)
Complications; N (%)	45 (18.9%)	12 (12.6%)	7 (16.3%)	4 (12.1%)	3 (15.1%)	18 (42.9%)	1 (20.0%)
Pain at prosthesis site; N (%)	31 (68.9%)	5 (41.7%)	5 (71.4%)	2 (50.0%)	2 (66.7%)	17 (94.4%)	-
Fever (>38°C); N (%)	3 (6.7%)	1 (8.3%)	2 (28.6%)	-	-	-	-
Redness and swelling; N (%)	18 (40.0%)	10 (83.3%)	4 (57.1%)	1 (25.0%)	-	3 (16.7%)	-
Retention; N (%)	10 (22.2%)	3 (25.0%)	1 (14.3%)	1 (25.0%)	1 (33.3%)	3 (16.7%)	1 (100%)
Within 3 months							
No complications; N (%)	197 (82.8%)	84 (88.4%)	32 (72.7%)	30 (90.9%)	18 (94.7%)	28 (66.7%)	5 (100%)
Complications; N (%)	30 (12.6%)	7 (7.4%)	6 (13.6%)	3 (9.1%)	1 (5.3%)	13 (31.0%)	-
Pain at prosthesis site; N (%)	16 (53.3%)	5 (71.4%)	1 (16.7%)	1 (33.3%)	-	9 (69.2%)	-
Fever (>38°C); N (%)	2 (6.7%)	1 (14.3%)	-	1 (33.3%)	-	-	-
Redness and swelling; N (%)	3 (10.0%)	1 (14.3%)	2 (33.3%)	-	-	-	-
Mechanical failure; N (%)	10 (33.3%)	-	4 (66.7%)	1 (33.3%)	1 (5.3%)	4 (30.8%)	-
Unknown if complications; N (%)	11 (4.6%)	4 (4.2%)	6 (13.6%)	-	-	1 (2.4%)	-
Other characteristics							
Using pads; N (%)	103 (43.3%)	17 (17.9 %)	32 (72.2%)	22 (66.7%)	15 (78.9%)	15 (35.7%)	2 (40.0%)
Patient can operate pump; N (%)	214 (89.9%)	83 (87.4%)	39 (88.6%)	31 (93.9%)	18 (94.7%)	38 (90.5%)	5 (100%)

*: No activation in first year of treatment

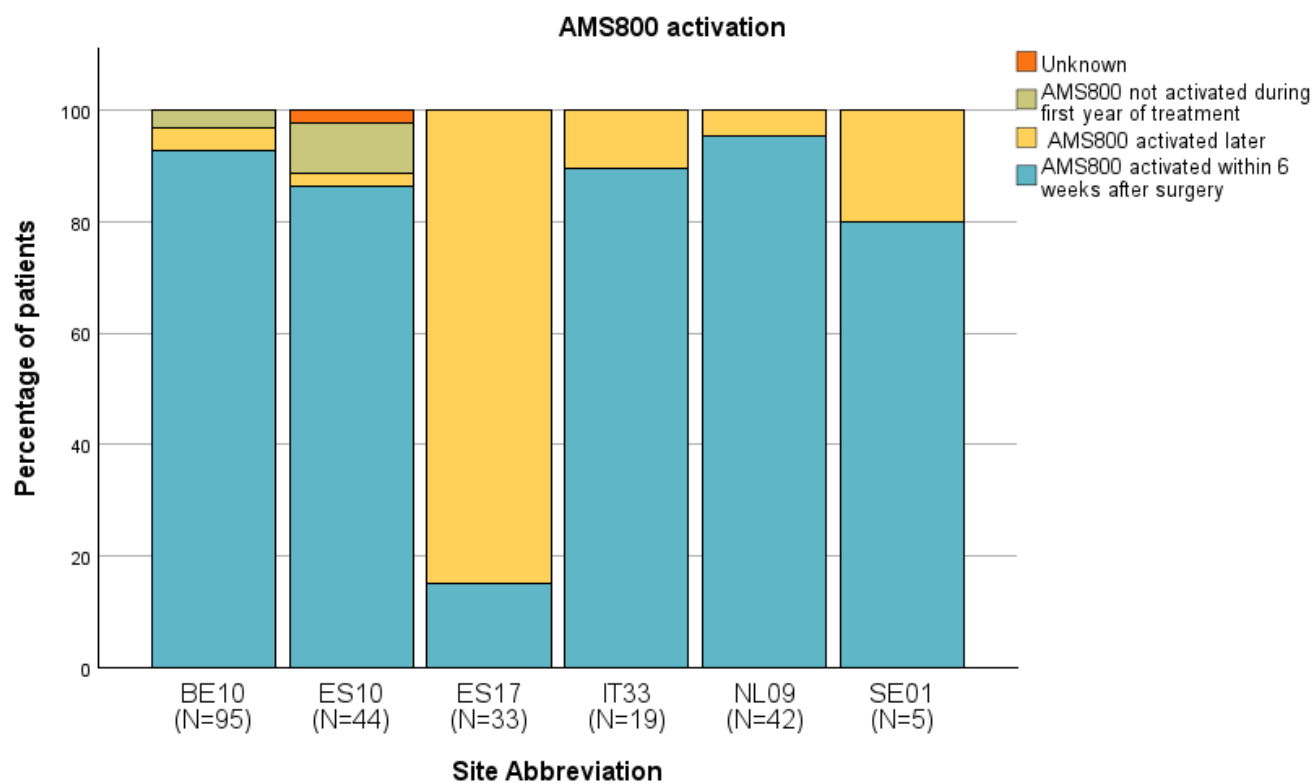
AMS800 implant surgery

The majority of patients received their AMS800 device when they were between 65 and 79 years old, with a peak at the age of 70-74 years.



Activation of AMS800 device

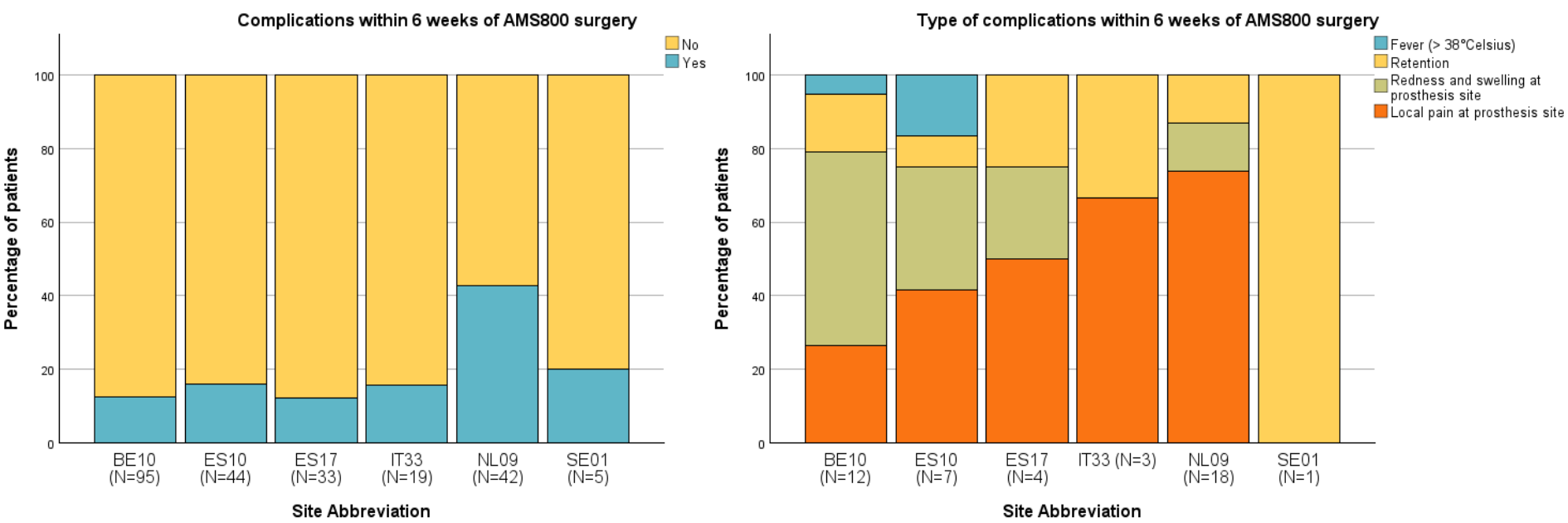
Almost all patients had their AMS800 device activated during the first year of treatment, most activations took place within 6 weeks after surgery, except at ES17.



Complications after surgery

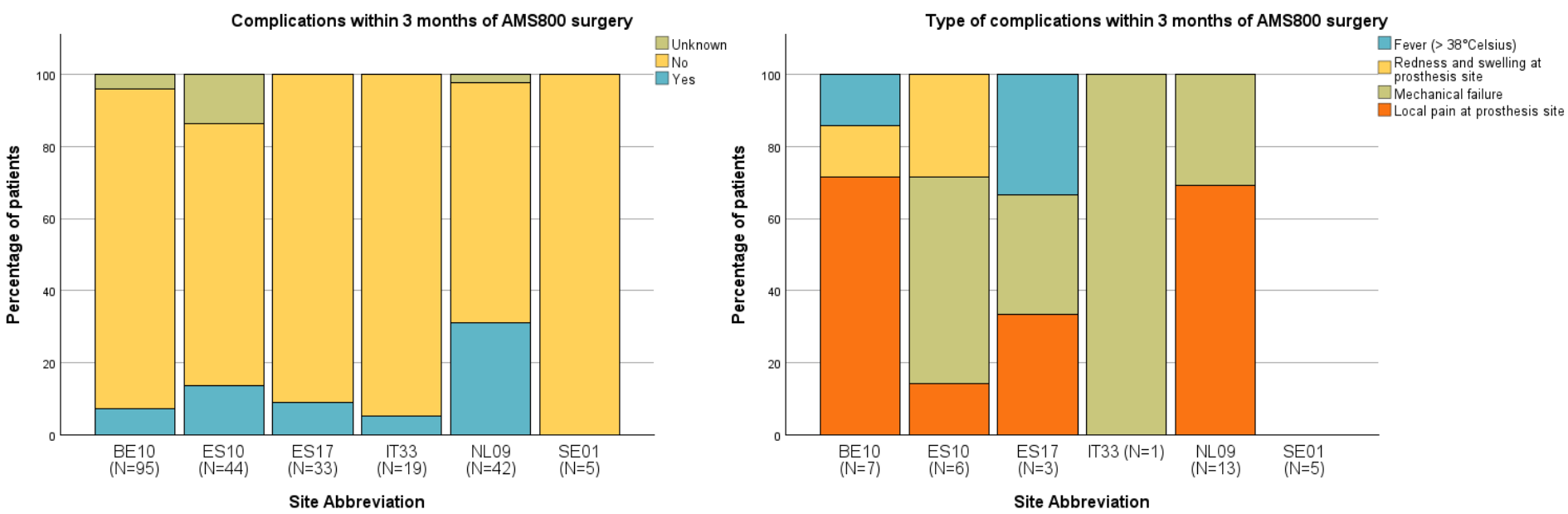
Within 6 weeks

Most patients did not experience any complications from their AMS800 surgery within 6 weeks. If patients had complications, the most frequent complication was local pain at prosthesis site.



Within 3 months

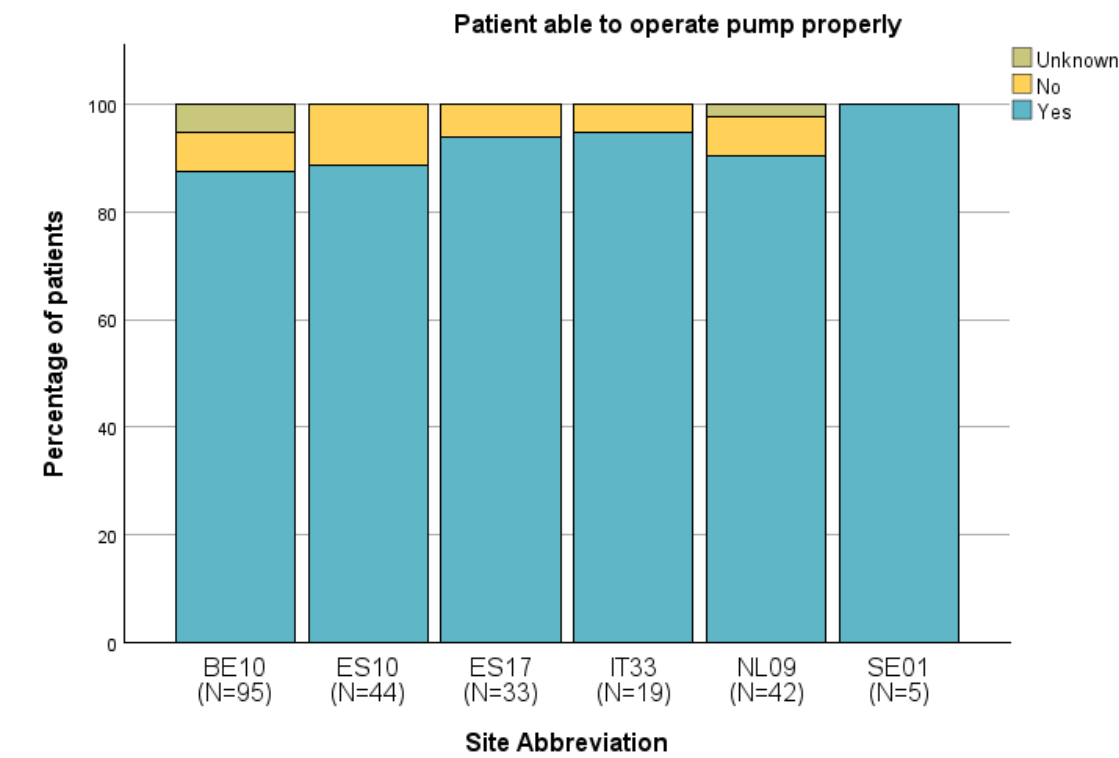
Again, most patients did not experience any complications within 3 months after the surgery. The most occurring complications were local pain at prosthesis site and mechanical failure.



Other characteristics

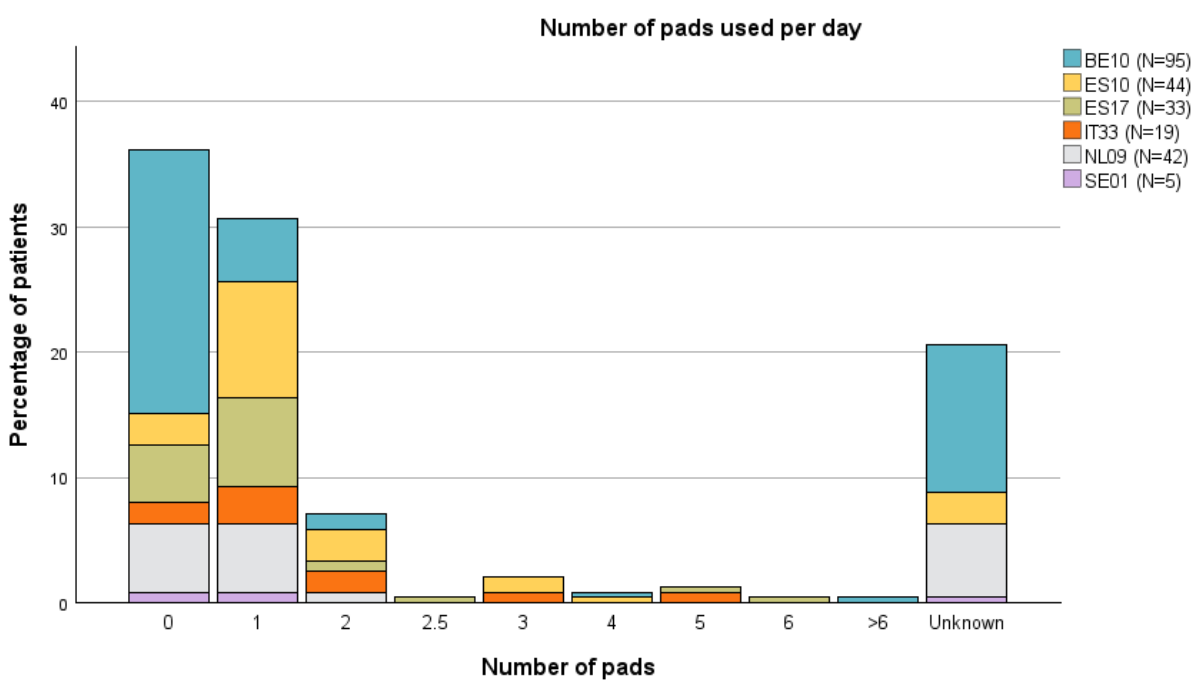
Patient can operate pump

Most patients were able to operate their pump properly.



Using pads

From the patients of whom use pads, most use pad one pad per day.





 **Network**
Urogenital Diseases
(ERN eUROGEN)

<http://eurogen-ern.eu/>



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<http://ec.europa.eu/health/ern>