Longitudinal Data from the Targeted Drug Delivery (TDD) Product Surveillance Registry: Pump Pocket Location

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Introduction

TDD with programmable intrathecal drug delivery systems (IDDS) has been approved for chronic malignant and nonmalignant pain treatment since 1991 and severe spasticity since 1992. Early clinical IDDS studies specified an "abdominal pocket" as the pump implant location, resulting in this as the defined on-label location. Alternate pump implant locations are often necessary for patient-specific reasons, but full evaluation of the risks and benefits of these alternate pump sites has not been performed. Presented are real-world registry data on the potential risks and benefits of alternate pump implant locations.

Background

A prospective, long-term, multi-center registry called the Product Surveillance Registry (PSR) enrolled patients implanted with IDDS, after providing informed consent. Patients are followed prospectively for events related to the device, procedure, and therapy, with device performance data collected. Investigators provide event descriptions, patient symptoms, and patient outcomes.

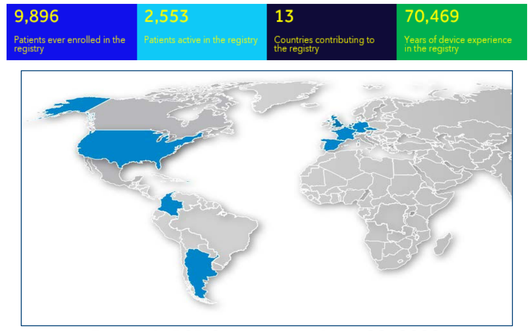

FIGURE 1: PSR STATUS AS OF APRIL 30, 2022

Between August 2003 and April 30, 2022, 9,896 patients from 13 countries were enrolled in PSR (Figure 1).

Methods

This analysis includes data from 12,472 IDDS patients with an abdominal wall or alternate pocket location in 9,896 patients enrolled through April 30th, 2022. The registry expanded its data collection in 2010; therefore, the cohort of patients (n=6,084) implanted with 7,415 pumps since 2010 was analyzed to compare anchoring techniques, antibiotic use, and complications between the abdominal wall and alternate pump implant locations.

Methods (cont.)

Procedure time and the rate of infection requiring surgical intervention were analyzed for initial pump implants (n=3,733). Within the 7,415 enrolled pumps, 2,855 (38.5%) were 20 mL and 4,560 (61.5%) were 40 mL reservoir pumps. Overall, 23.2% (1,723/7,415) of the pumps were implanted in a location other than the abdominal wall (Figure 2).

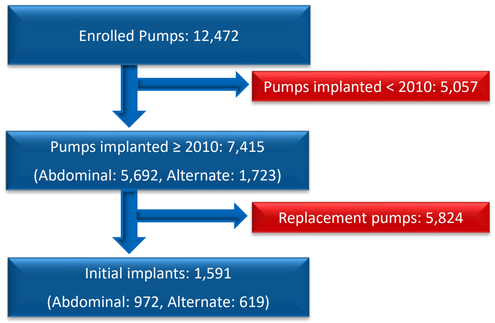

FIGURE 2: PUMP DISPOSITION

In 2022, 45.4% of the pumps were alternate pump pocket implants (Figure 3).

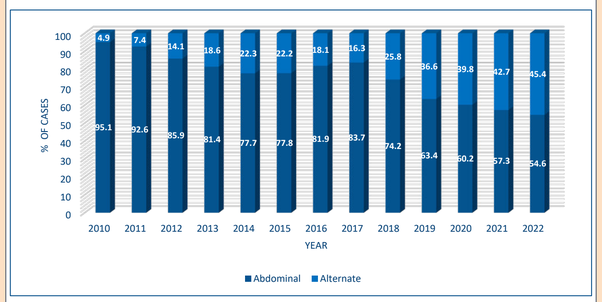

FIGURE 3: IMPLANT LOCATION BY CALENDAR YEAR

Of the pediatric (<18 years) implants since 2010 (n=346), only one was implanted in a non-abdominal location. Therefore, sub-analysis on pediatric vs adult implants was not performed.

Results

Pump anchoring technique was summarized for 7,415 pump implant procedures occurring after 2010, with the predominant anchor technique, excluding "Other", for both implant locations being suture loops (Table 1). The majority of abdominal wall implants (66%) used >2 suture loops while the majority of the alternate cases (76.1%) used ≤ 2 suture loops.

TABLE 1: PUMP ANCHOR TECHNIQUE*

Anchor Technique	Abdominal	Alternate
Mesh pouch not sutured	316/5692 (5.6%)	18/1723 (1.0%)
Mesh pouch sutured	1048/5692 (18.4%)	170/1723 (9.9%)
Suture loops	4042/5692 (71.0%)	734/1723 (42.6%)
Other[a]	621/5692 (10.9%)	864/1723 (50.1%)

[a] Includes other, specified anchoring methods, which may include not anchored or unknown.
*More than one anchoring technique may be used; percentages not expected to sum to 100%

Antibiotic use for pre-operative and post-operative techniques was similar for both implant locations. However, the rate of intra-operative antibiotic irrigation performed in the abdominal implant group was 40.8% (2,325/5,692) versus 66.7% (1,150/1,723) in the alternate implant group.

The overall surgical modification (other than explant) rates for the abdominal wall and alternate implant location were 4.6% and 3.1%, respectively (Table 2).

TABLE 2: SURGICAL MODIFICATIONS

Surgical Modifications	Abdominal	Alternate
Surgical modifications (excluding explant)	**262/5692 (4.6%)**	**54/1723 (3.1%)**
Surgical repositioning	190/5692 (3.3%)	39/1723 (2.3%)
Other surgical modifications	89/5692 (1.6%)	16/1723 (0.9%)

The median procedure duration for implants in the abdominal wall was 24 minutes longer than alternate implant locations (Table 3).

TABLE 3: PROCEDURE TIME (MINUTES)

Pocket Location	N*	Mean (SD)	Median (Min-Max)
Abdominal	972	69 (38)	60 (11 – 370)
Alternate	619	46 (25)	36 (5 – 212)

* Procedure time for initial implants was documented for 1,591 pump implant cases.

Events collected in the registry include device, procedural and therapy related events. Table 4 presents (1) the overall rate of events and (2) device movement events that occurred after the registry expanded the scope of adverse event data collection in April 2010.

Results (cont.)

TABLE 4: EVENT RATES (OVERALL AND DEVICE MOVEMENT)

Event Type	Abdominal		Alternate	
	Events	Patients % (n/N)	Events	Patients % (n/N)
Overall Events*	8638	49.2% (2318/4714)	2830	65.8% (929/1412)
Catheter dislodgement	217	3.8% (178/4714)	125	6.5% (92/1412)
Pump flipping or migration	312	4.5% (212/4714)	35	2.1% (29/1412)

*Excludes deaths unrelated to the device, procedure, or therapy.

There were 115 infections requiring a surgical intervention in 113 of the 3,740 therapy-naïve patients. The rates of infection among therapy naïve patients requiring surgical intervention are summarized in Table 5.

TABLE 5: RATE OF INFECTIONS REQUIRING SURGICAL INTERVENTION

Pocket Location	No. of patients	No. of infections requiring surgical intervention	Percent of patients (n/N)
Abdominal	2653	93	3.4% (91/2653)
Alternate	1087	22	2.0% (22/1087)

Discussions

The median procedure duration was over 20 minutes shorter for registry patients with an alternate pump placement compared to an abdominal placement assumed to be due to differences in patient position during the implant procedure. Overall surgical modifications (excluding explant) were similar between the pump implant placement groups. Overall event rates were >12% higher in the alternate implant group compared to the abdominal group, and the data suggest potentially different risk profiles for certain events with a higher observed rate of catheter dislodgement and lower observed rate of pump flipping/migration in the alternate implant group compared to the abdominal pump implant group. The data suggest that alternate pump implant location may improve the risk profile for certain events (i.e., pump migration) with potential worsening of others (i.e., catheter dislodgement).

Conclusions

Implant technique for IDDS varies by physician with the location of pump pocket placement often determined by patient anatomy and other factors as determined by the implanting physician. This data indicates an increasing number of pumps being implanted in locations other than the abdominal wall. Important surgical considerations and specific patient factors are assessed on an individual basis, but data presented here indicates further evaluation of the risks and benefits associated with the alternate implant locations is warranted.