Preventing Peripheral IV Failure: The Next Big Thing In Vascular Access Adjunct Products

Products that prevent peripheral IV failures could be the next big thing in the market for vascular access adjunct products, a market opportunity valued at more than $600MM in the US alone, according to SmartTRAK estimates.

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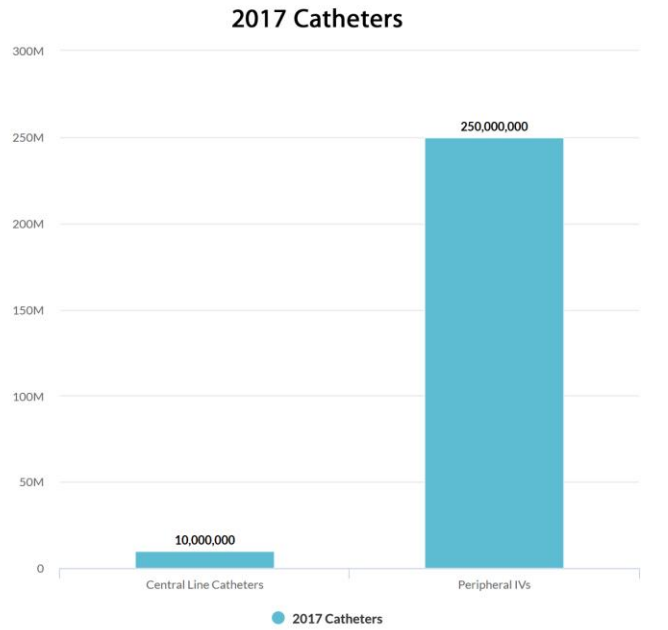
The high failure rate of peripheral IVs (PIVs) was front and center at the recent Association of Vascular Access (AVA) 2018 Annual Scientific Meeting where the latest research and innovation focused on clinical practice, protocols and products for improving patient care and preventing PIV failure. Many speakers highlighted the 2015 article by Helm et al. "Accepted but Unacceptable: Peripheral IV Catheter Failure" which estimates a PIV failure rate of 35% to 50%, primarily caused by phlebitis, infiltration, occlusion/mechanical failure, dislodgment and infection. Failure is defined as the removal of the catheter prior to the end of its intended life or before the 72 to 96 hours previously used as a guideline. And with up to 90% of all hospitalized patients receiving a PIV, it is a standard but often overlooked procedure in the hospital.

The primary emphasis over the last 10 to 15 years has been the reduction of catheter-related bloodstream infections (CRBSIs) associated with central line catheters. Driving this focus has been CMS reimbursement penalties for hospital acquired central line bloodstream infections (CLABSIs). This new focus on PIVs could be exciting for manufacturers, especially those with adjunct vascular access products. Clinicians insert approximately 250 million PIVs every year in the US (assuming a 25% failure rate on first insertion), a market that is 25 times larger than the US market for central line catheters.

In a presentation at AVA, Russell Nassof, JD, urged clinicians to take a close look at clinical practice guidelines in their facility to ensure their protocols are current and reflect best practice. This recommendation opens the door for clinicians to challenge current practice and implement new protocols and products that improve patient care and reduce PIV failures. (See Figure 1.)

With an increased focus on PIV failures, prevention is becoming a top priority, potentially expanding the market for vascular access adjunct products and creating a market opportunity exceeding $600MM according to *SmartTRAK* estimates. In this article, *SmartTRAK* highlights new PIV products and technologies, many showcased at AVA 2018, that could serve the needs of this long-neglected market segment.

Figure 1



Source: *SmartTRAK Infection Prevention Vascular Access*, *BioMedGPS LLC*

Expanded Opportunity for Antimicrobial Devices

There is growing interest in antimicrobial PIV products, as data suggests many CRBSI's currently attributed to central line catheters may actually originate with PIVs. At AVA 2018, several presenters referenced Helm et al.'s article that estimates the percent of CRBSI's related to peripheral venous catheters ranges from 0% to 2.2%. Russell Nassof, JD estimated the percent at 0.2%, which translates into almost 500,000 CRBSIs attributed to PIVs.

The leading antimicrobial device on the market today is Ethicon's BioPatch, which is currently indicated for the reduction of CRBSI's in patients with central venous or arterial catheters. Launched in 2002, BioPatch has a head start on the PIV market with revenue of almost $110MM in 2017 and 75% share according to SmartTRAK estimates. With high penetration of antimicrobial devices and increased competition for reduction of central line infections, Ethicon has begun pursuing adjacent opportunities. The Company has been recommending the use of BioPatch for PIVs for several years and has been collecting clinical evidence to help support the use of the product. In a case study of a 674 bed hospital, the implementation of Biopatch on PIVs resulted in a 37% reduction in house-wide confirmed bloodstream infections and a 19% reduction in PIV related BSIs.

There are several other companies pursuing the PIV market with antimicrobial products but with lower cost alternatives. In 2012, Covalon received 510(k) clearance for IV Clear, a self-adherent, antimicrobial dressing used for securement of devices and covering/protecting insertion sites which includes a silicone adhesive impregnated with CHG and silver. Although approved several years ago, the product has not gained significant traction in the US. However, it has been received positively in the Middle East where the Company won significant tenders, including one valued at $100MM over three years related to its IV Clear, ColActive Plus as well as several products in its CovaWound line. In the US, Covalon has recently decided to go to a direct sale model rather than be an OEM supplier which may explain their limited success in the US to date.

3M, a leader in IV dressings and antimicrobial products to reduce catheter related infections, recently launched Tegaderm Antimicrobial IV Advanced Securement Dressing designed for PIV sites at roughly a quarter the cost of BioPatch. The product, a transparent dressing that integrates CHG throughout the adhesive, suppresses normal skin flora regrowth on prepped skin for up to 7 days.

In a recent survey supported by 3M and conducted by a third party research firm, 50% of 650 US infection preventionists and clinicians agreed that peripheral line associated bloodstream infection pose a real threat to patients in acute care settings.

New entrant, Entrotech Life Sciences launched its phrevahex CHX antimicrobial dressing at AVA 2018 touting its unique benefits, which incorporates pure chlorhexidine, eliminating other components and creating a longer-lasting antimicrobial with less skin irritation. In a poster presentation at the meeting, a study comparing prevahex CHX Antimicrobial Dressing to a non-securement, non-antimicrobial dressing on 207 PIV insertion sites found the CHX securement dressing was significantly more likely to last to therapy completion and contributes to lower overall phlebitis and infiltration rates.

Over the last several years, BD has been working with Avery Dennison to develop ChloraShield IV, a transparent adhesive dressing. The product was initially FDA cleared in 2011 and received an additional clearance for ethylene oxide sterilization in mid-2017, but has yet to be launched on the US market. ChloraShield IV is a transparent film dressing with a CHG impregnated acrylic adhesive. BD/CareFusion has shown the product on and off at AVA meetings over the past few years so its future has been uncertain. However, at this year's AVA meeting, *SmartTRAK* learned the Company was sharing information on the product to select individuals. Full launch of ChloraShield is now expected to take place mid-2019 and will broaden BD's portfolio of adjunct products to support intravenous catheters.

So how big is the potential opportunity for these devices? If one assumes the average cost of a non-antimicrobial transparent securement dressing today runs about $0.75 and the cost of these new antimicrobial dressings ranges from $1.50 to $6.00 (for BioPatch), the market potential for these new products is ~$450MM in the US alone. That's an immense increase over *SmartTRAK*'s estimated $142.6 MM in US revenues for antimicrobial devices/dressings in 2017. Conservatively, even if only 20% of the market converts to antimicrobial PIV devices, it is still a $90MM increase in market size from 2017.

Innovation in Securement Devices

Securement is also an issue for PIVs as poor securement leads to phlebitis, dislodgement and infection. A variety of products are used today for securement and include basic film (polyurethane) dressings, film dressings with stabilization, and mechanical securement devices. 3M holds the leadership position in dressings with its Tegaderm line of products while BD leads the mechanical securement with StatLock, although it is primarily used on PICC lines and its use to date on PIVs has been limited. Some type of securement is used on most PIVs today, with cost varying from basic film dressings at $0.25 to mechanical devices at roughly $5.00.

In addition to the focus on peripheral IVs, perhaps the next hottest topic at AVA 2018 was Adhezion Biomedical's SecurePortIV, a new catheter securement adhesive for both securement and site protection. The product was FDA cleared as a 510(k) Class II medical device in 2017 and is the first such product type approved for these indications in the market. The product would ideally be used in addition to current securement products for its benefit in stabilizing the device at insertion, but also for sealing the insertion site from bacteria - ultimately reducing catheter movement, migration, and dislodgement while providing a unique defense against infection. There have been numerous published papers related to the use of tissue adhesive to reduce catheter complications providing the foundation for adoption in the market. A large clinical study published in the *Lancet* on the use of tissue adhesives for PIVS reported advantages in failure rate, occlusion and dislodgment. The use of the product will be impacted somewhat by its cost, estimated to be ~$5.00 per application.

In terms of mechanical securement devices as mentioned, StatLock owns the securement market today and has limited competition. The product was launched nearly 20 years ago and has seen few improvements but continues to own the lion's share of the market as BD controls the products included in its IV insertion kits. However, Starboard Medical is taking on BD and StatLock with its Clik-FIX device, a lower cost, potentially better performing product. In a presentation at AVA, researchers reported the results of a study conducted at a large medical facility that compared Clik-FIX to the industry standard securement device for PICC lines. Clik-FIX

demonstrated advantages in application ease of unlocking, securement, durability and adhesive sensitivity. The study presenter noted it took over a year to go through the necessary committees to gain approval to test the device due to the strength of BD and StatLock in the market. Click-Fix may become a more attractive option if hospitals need to balance the total cost associated with PIV care.

Assuming additional cost for securement would primarily lie with the use of SecurePortIV at ~$5.00, the total market opportunity estimated by SmartTRAK would be $1.25B and with only a 20% adoption for PIVs, a $250MM market exists.

Novel Break-away Products Target Dislodgement

PIV dislodgement is also a significant clinical and economic challenge for healthcare providers. A study presented at AVA estimated the PIV dislodgment rate at 10.8%, while prospective clinical trials highlighted in the Helm et al. publication suggest between 6.9% and 17.5% of all PIVs become dislodged. In another AVA presentation, a prospective study of 51 consecutive patients that experienced catheter dislodgement found the average time to reestablish a PIV was 55 minutes at an average cost of $47.58, with 75% of that cost being materials. Assuming an 11% failure rate and the cost of a restart, the overall cost of dislodgment to the US healthcare system amounts to a whopping $1B or more every year.

Two companies are paving the way and creating a new segment in the market by developing novel breakaway products to address this clinical need. Lineus Medical, founded in 2015 and the furthest along, is developing SafeBreak Vascular a device having a "break-away" mechanism that fits into all standard IV lines and is designed to separate at 3.7 pounds. Experts say cognitive impairment is the primary cause of catheter dislodgement and therefore Lineus is conducting a 40-patient clinical study to evaluate the use of SafeBreak in a geriatric trauma unit with the primary outcome dislodgement in seven days. Spencer Jones, Lineus' CTO and Founder told SmartTRAK, the Company's initial focus after launch will be on PIVs for individuals having cognitive impairment, estimated to be 25% to 30% of all PIVs and PICC lines. The Company has filed for FDA clearance and hopes to have clearance by year-end 2018.

In addition to Lineus Medical, another company targeting IV dislodgments is Linear Health Sciences. The Company emerged this year at AVA with its Orchid Safety Release Valve for preventing dislodgments caused by macro forces on an IV. The device connects directly to existing luers and includes a proprietary valve design to ensure a sterile barrier upon valve activation. Linear Health sponsored a survey conducted by Nancy Mourea, RN, PhD, CRNI, CPUI, VA-BC to access the incidence and types of accidental dislodgement of IV catheters in the acute

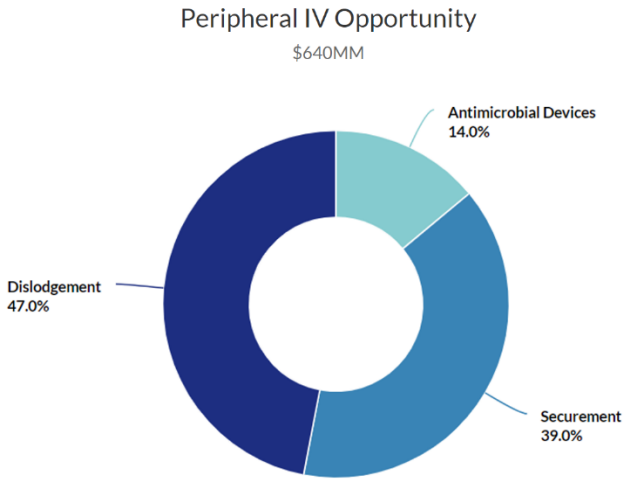
care setting. Nurses completing the survey responded that dislodgement is a significant unaddressed problem at their facility with short PIV catheters cited most often, followed by midline, PICCs and CVCs. The Company hopes to provide an economical solution that will allow break-away devices to be used on all catheter lines. CEO Ryan Dennis, MD, commented "The team at Linear health is excited to see market launch approaching in early 2019. The company's extensive R&D efforts across multiple safety release valve applications will continue to move healthcare towards a safer more efficient standard of care for how we connect patients to their treatments."

With the average cost of these emerging products between $4.00 and $8.00 per device, the market potential for breakaway devices is a whopping $1.5B for PIV applications according to *SmartTRAK* estimates. With just 20% penetration, that translates into an impressive $300MM market for these devices.

Market Opportunity, Adoption and Growth

The failure of PIVs provides an incredible opportunity, estimated at $640MM assuming only 20% penetration for vascular access adjunct products to reduce failure rates. However, with the focus on preventing CLABSIs, little has been done to document the failure of PIVs in the acute care setting. As a result, adoption will be slow until documentation of failure is obtained by acute care facilities or CDC guidelines are established. Initial adoption will occur in patient segments with high risk for failure such as pediatrics, those with cognitive impairment or infection. (See Figure 2.)

Figure 2



Source: *SmartTRAK Infection Prevention Vascular Access, BioMedGPS LLC*

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