

AN ALERT SYSTEM FOR INTRAVASCULAR ACCESS DEVICE DISLODGEEMENT (ASIVAD) (Tel Hashomer)
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Abstract

Placement of an intravascular access device (IVAD) into a vein or an artery of a patient provides at times critical access to the patient's blood circulation. Inadvertent dislodgement of the IVAD from the patient's blood vessel is a constant risk that may result in venous or arterial bleeding with catastrophic consequences, for example massive blood loss during dialysis or hemofiltration or discontinuation of infusion of a life-sustaining drug on which the patient's life depends

The potentially disastrous and life-threatening consequences of inadvertent IVAD dislodgement have led scientists and the health-related industry to seek safety devices that would prevent such catastrophic event from occurring. A few such devices have been proposed over the years, but very few have matured to clinical practice and none has yet become standard of practice, most likely because of considerations relating to cost-effect.

The Need

There is currently no available alarm system that can alert the patient or the medical team to the accidental dislodgement of an IVAD from the blood vessel, or an automated monitoring system that can stop, under such conditions, the blood pump or infusion device. As a consequence of such event, unnoticed massive blood loss or discontinuation of infusion of a critical life-sustaining drug can occur, leading to grave consequences and life threatening clinical complications, at times fatality.

The need is obvious in a variety of clinical settings, but stands out in hemodialysis during which venous needle dislodgement has been recognized as one of the most serious accidents that can occur in which the patient can bleed to death within minutes. The drop in venous pressure in the system following venous needle dislodgement is usually delayed and insufficient to trigger an alarm within the hemodialysis machines. Fatal or near fatal blood loss is an inevitable consequence that has been described and discussed on multiple occasions. The reported yearly incidence of accidental dislodgement of an IVAD from the blood vessel is ~1.2 per 1000 patients and up to 1/3 result in fatality. Published reports are likely, however, to represent only the tip of the iceberg, as such incidents are usually handled at a local or national level and are not publicized and the extent of the problem is likely to be several fold the one reported. It is therefore likely that the true incidence of

accidental access dislodgement is ten-fold higher than that reported, i.e. 1.2 cases per year per 100 patients. The magnitude and importance of the problem in hemodialysis is in fact such that the American Nephrology Nurses' Association resorted to setting up a special project workgroup that recognized the magnitude and the importance of the problem and that came up with 12 recommendations how to minimize the risks of accidental dislodgement of an IVAD.

Recommendation 12 consists of the statement that "additional protection can be provided by devices intended to detect blood loss from the needle site to the environment". The problem raises an urgent need for an engineered solution. Requirements for such a solution include: reliable detection of needle position, a useful alarm, and feedback to stop the blood pump. Our device addresses all three needs and provides a superior solution to that recommended by American Nephrology Nurses' Association in that it comes to detect the actual dislodgement of the IVAD from the blood vessel, which antecedes and prevents actual blood loss.

The incidence of IVAD dislodgement in plasmapheresis, or in any of the other applications of the device we are proposing, is largely unknown and its impact has not been addressed or evaluated by health authorities, even though its potentially catastrophic sequelae are not less than in hemodialysis.

The Technology

Our technology (ASIVAD) provides an alert system for continuous or periodic monitoring of the proper placement of the IVAD and for immediate detection and alerting in case of dislodgement and automated interruption of the blood pump or infusion device.

The novel technology and product is simple to implement and use in any clinical setup, inexpensive, and provides the perfect solution (ASIVAD) to the problem of inadvertent IVAD dislodgement.

Our platform technology can be applied in a large spectrum of medical conditions in which such event can lead to an immediate life-threatening situation:

The Product

We provide hereby a simple system and device, inexpensive, and straightforward technological solution (ASIVAD) to the problem of inadvertent IVAD dislodgement that can be applied, with very few modifications, to a large spectrum of medical conditions in which such event can lead to an immediate life-threatening situation. The simple design of the device, its widespread applicability and its low cost should render it highly attractive to the health industry that places "safety first".

Applications

—**Hemodialysis** is the immediate application of the alarm system. During hemodialysis, two large gauge needle are inserted into the patient's vascular access (e.g. shunt or fistula) in order to draw blood from the patient (arterial side), and to return to the "purified" blood (venous side). Both needles, after being inserted through the skin into the vascular access, are secured and fixed onto the patient's skin with medical tape. Duration of dialysis averages 3-4 hours, during which the patient tends to randomly move, putting the needles at risk of being inadvertently pulled out of the vascular shunt, resulting in major bleed and blood loss. When the needle on the "venous side" is inadvertently pulled out, the results might be catastrophic, as blood continues to be pumped out at a fast rate of 300-400 ml/min, and instead of being returned into the patient's circulation, flows freely and unnoticed on the patient's clothing or floor. Dialysis machines do not offer any early alarm or fail-safe system for such scenario.

Plasmapheresis is the another condition requiring high blood flow through an extra-corporal device and dual IVAD. Accidental unnoticed dislodging of the intravenous access through which blood is withdrawn for plasmapheresis, or of the needle through which blood is returned to the patient, may result in excessive and life endangering blood loss.

Intravenous infusion of a life sustaining drug: For example, a patient in the intensive care setup in septic shock who is hypotensive is being infused noradrenaline to sustain systemic arterial pressure. Accidental but unnoticed dislodging of the IVAD may result in interrupted delivery of nor-adrenaline to the patient and catastrophic consequences.

Infusion of essential fluids, nutrition or drugs to neonates, where accidental dislodging of the needle could prevent administration of essential life-sustaining components.

This alert system can also be applied to any other clinical condition during which fluids or drugs need to be infused intravenously, and accidental unnoticed dislodgement of the vascular access prevents the intended fluid or drug delivery.

Our innovated technology and product, its widespread applicability and its low cost should render it highly attractive to the health industry that places "safety first".

The Market

Dialysis Over 2 million people worldwide currently are treated with dialysis. More than 80% of all patients who receive treatment for kidney failure are in affluent countries with universal access to health care and large elderly populations. It is estimated that the number of cases of kidney failure will increase disproportionately in developing countries, such as China and India, where the number of elderly people are increasing and healthcare is improving due to better economic conditions. Dialysis is performed 13 times/month, every month of the year - amounting to 156 dialysis or 156 ASIVAD devices per patient per year, or 312 million ASIVAD systems worldwide.

Plasmapheresis has a very wide range of clinical applications, most commonly for a variety of neurologic, immunologic or hematologic disease. A patient can need as many as five treatments per week over many weeks. The estimated market potential is not less than the world dialysis population.

Intravenous infusion of life sustaining drugs is a very common occurrence in any medical or surgical department as well as in intensive care units in every hospital setting worldwide. More than 5.7 million patients are admitted annually to intensive care units in the United States alone

Infusion of chemotherapy to oncologic patients is a standard and widely used procedure in any oncologic clinic or in hospital department worldwide. The number of new cancer patients has been estimated as 14 million per year worldwide, and this number is expected to increase by as much as 70% during the next two decades.

Infusion of fluids, nutrition or drugs to neonates is commonly used in neonatal intensive care units. If 361,481 babies are born each day around the world, 10-15% winds up in the neonatal intensive care unit for a variety of reasons, creating a huge yearly work load on these units of almost 13million patients.

In summary, the marketing potential for the IVAD displacement alert system is estimated to cover a minimum of 40 million patients per year, many of whom will require a large number of these systems in the course of each year.

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