Advances in surgical tourniquets

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Every year in North America, an estimated 10,000 surgical tourniquets are used in approximately one million procedures. Despite the almost universal use of such tourniquets for surgery of the extremities, recent studies show every use results in some injury to the patient. The nature, extent, and duration of such injuries are largely a result of characteristics of the tourniquets used.[1] Increased awareness of tourniquet-related injuries and hazards may lead to the development of new standards for surgical tourniquets.[2]

The history of nonpneumatic and pneumatic tourniquets in surgery has been reviewed extensively.[3] It is recorded that Roman surgeons used constricting devices for amputation. In 1718, the French surgeon Jean Louis Petit developed a screw device for hemostasis. Because of its turning action, Petit called the device a tourniquet. Tourniquets were first used in surgical procedures other than amputations in 1864. Figure 1 shows a nineteenth century tourniquet from an amputating and general surgery set.

Since that time, three technical advances have facilitated the development of bloodless-field surgery:

- the introduction by Esmarch of an elastic-wrap bandage for exsanguination of a limb before tourniquet application
- the introduction of a pneumatic tourniquet by Cushing in 1904
- the development of an automated, microprocessor-based tourniquet in 1982.

The use of tourniquets in surgery has been acompanied by reports of limb

Fig 1. A nineteenth-century tourniquet from an amputating and general surgery set. (From the Mütter Museum collection at the College of Physicians of Philadelphia. Photo by Rick Echelmeyer.)

Table 1

Hazards, clinical signs, and possible causes of injury associated with conventional surgical tourniquets

Hazard	*Clinical signs*	*Possible tourniquet-related causes*
1. Overpressurization	Tourniquet paralysis	Malfunctioning pressure regulator
	Postoperative muscle weakness	Excessive hysteresis in pressure regulator
	Pain at cuff site	Inaccurate pressure gauge or sensor
	Other compression injuries to blood vessel, nerve, muscle, or skin	Lack of audiovisual alarms
		Infrequent monitoring by staff
		Improper setting of tourniquet pressure
2. Underpressurization	Blood in surgical field	Malfunctioning pressure regulator
	Passive congestion of limb	Excessive hysteresis in pressure regulator
	Shock	Inaccurate pressure gauge or sensor
	Hemorrhagic infiltration of nerve	Lack of audiovisual alarms
		Infrequent monitoring by staff
		Improper setting of tourniquet pressure
		Kinking of hose to cuff
		Geometric mismatch of cuff and limb
		Cuff failure
		Loss of pressurized gas source
		Large leaks of cuff or hose
		Disconnection of cuff or hose
		Intraoperative increase in systolic pressure
3. Excessive period of inflation	Tourniquet paralysis	Infrequent monitoring of elapsed time
	Postoperative muscle weakness	Lack of audiovisual alarms to warn of excessive inflation periods
	Ischemic injury distal to cuff	
	Excessive postoperative reactive hyperemia	
4. Improper cuff application or perioperative procedures	Venous congestion	Improper preoperative exsanguination
	Soft tissue injuries (bruising, blistering, pinching, necrosis of skin)	Slow inflation or deflation
		Incomplete or overly aggressive seal at cuff
	Chemical burns at cuff	Pooling of preparation solutions
		Cuff geometry or physical characteristics

paralysis, nerve damage, and other injuries. These complications may result from (1) overpressurization, (2) underpressurization, (3) excessive period of inflation, or (4) cuff-related factors, such as improper cuff application. The most common cause is overpressurization. Table 1 contains a summary of hazards, clinical signs, and possible causes of injury associated with conventional tourniquets.

The actual incidence of tourniquet-induced complications cannot be estimated accurately. Because the damage

is generally transient and is reversible to a large extent, the "tourniquet paralysis syndrome" may be difficult to detect or may be masked by the effects of surgery. In addition, incidents with tourniquets during surgery may not be consistently reported because of concern about potential legal liability. For example, a hospital was recently found liable for the nerve injury suffered by a patient as a result of excessive pressure applied to her arm by a tourniquet.[4]

Early in 1982, a manufacturer announced the availability of the first commercial microprocessor-based tourniquet. This type of tourniquet promises to improve safety and performance significantly and, at the same time, reduce the operating costs now associated with conventional tourniquets. This paper will indicate the potential of such a tourniquet, based on data collected over a 30-month period and which concerned incidents, hazards, and operating costs of conventional tourniquets.

Pneumatic tourniquets that are currently available consist of three basic components: a cuff similar to a blood-pressure cuff, which is wrapped around a patient's limb and inflated with gas; a source of compressed gas; and a pressure gauge with a mechanism designed to maintain pressure in the cuff at a desired value.

During a 30-month period, 12 surgical tourniquets (Kidde Model 400 Pneumatic Tourniquets) were given 84 safety and performance inspections at scheduled intervals by our hospital's biomedical engineering department. In addition to these scheduled inspections, the 12 pneumatic tourniquets were also given 71 unscheduled inspections as a result of reported incidents, hazards, or malfunctions. Results of the 84 scheduled inspections are given in Table 2. Criteria for failure in these tests are

1. hysteresis, or error in the pressure regulating mechanism of 200 mm Hg or more
2. leaks sufficiently large to cause visible depletion of the compressed-gas reservoir
3. pressure gauge that would not return to zero on depressurization
4. error in pressure gauge of 10% or more
5. maximum cuff pressure of 1100 mm Hg or more
6. drift in set pressure of more than 10% over a 15-minute period
7. significant physical deterioration of one or more major components.

Hysteresis indicates the pressure relief valve and the pressure source in the regulator of the tourniquet turn on and off at different levels. For example, a pressure regulator having a hysteresis of 200 mm Hg may prevent pressure from falling significantly below the set level but permit it to rise an additional 200 mm Hg. Or the same regulator may prevent a significant rise in pressure but permit it to fall to 200 mm Hg below

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Test procedures

In inspecting tourniquets, an accuracy test is first performed by checking test gauge readings at set pressures in the tourniquet of 0, 100, 300, and 600 mm Hg, in increasing and then decreasing order. The effect of tapping on the aneroid gauge at each pressure is noted. Any effect greater than 15 mm Hg is considered unacceptable.

Hysteresis tests are conducted by connecting a rubber bulb from a sphygmomanometer via a T-piece adapter between the tourniquet cuff and controller. The cuff is then inflated to 300 mm Hg. The bulb is used to increase the pressure until a plateau is reached on the tourniquet gauge and is recorded. The pressure is then slowly decreased through the bulb until a constant pressure value is reached. The difference between the two plateau pressures represents one hysteresis value. A second hysteresis value is obtained by repeating the procedure but approaching a pressure of 300 mm Hg from a higher pressure of 500 mm Hg.

The stability test is performed by setting the tourniquet at a pressure of 550 mm Hg from a pressure at least 200 mm Hg higher. The hose at the cuff is occluded with a hemostat and the indicated pressure is observed after 15 minutes. The pressure should not have increased noticeably, and it should not have decreased by more than 10%.

The physical condition of the tourniquet—including the aneroid gauge, cuff, tubing, connectors, valves, and pressure regulating mechanism—is also examined to determine if any components have deteriorated or have been damaged and require replacement.

the set level. Whether high pressure or low pressure is allowed depends on how the device was adjusted initially.

The failure of any tourniquet in any one of the seven tests summarized above constitutes a significant hazard. The results summarized in Table 2 indicate the tourniquets tested are hazardous and unreliable. Further, the constant need to monitor and manually control such tourniquets because of their unreliability makes their safe use unnecessarily labor-intensive. Aside from the hazards and labor costs associated with their use, the annual cost of repairing and testing pneumatic tourniquets is high in relation to their cost. Over the 30-month period, our costs (in US dollars) for 12 tourniquets was $1,139 for parts and $2,683 for labor. This amounted to $127 per tourniquet each year, compared with a tourniquet's cost of about $480. In view of the results of these inspections, we suggest that other hospitals consider similar programs.

Despite our hospital's regular interval inspections of tourniquets for possible hazards, 55 tourniquet-related incidents were reported by hospital staff and investigated over the 30-month period. Of these incidents, 10 (18%) were related to hazardous overpressurization, 17 (31%) to hazardous under-

Table 2

Results of 84 tests of conventional tourniquets

Criteria	*Failures*	
	%	*Number*
1. Hysteresis over 200 mm Hg	49	41
2. Visible leak	5	4
3. Nonzero pressure gauge	4	3
4. Pressure-gauge error over 10%	13	11
5. Maximum cuff pressure over 1100 mm Hg	5	4
6. Pressure drift over 10% in 15 minutes	5	4
7. Physical deterioration	45	38

For most patients, soft tissue injuries were relatively minor.

pressurization, and 28 (51%) to soft tissue injuries.

The 10 incidents attributed to overpressurization included 3 cases of tourniquet paralysis of the upper limb. Subsequent physical examination and electromyographic analysis identified a nerve block at the cuff site in each of these patients. In all 3 cases, the tourniquet paralysis largely resolved over a period of several months. In 9 of the cases, the cause of the overpressurization was a malfunctioning pressure regulating mechanism, or one that had hysteresis of more than 200 mm Hg.[5] In the tenth case, the pressure gauge was found to have an error greater than 200 mm Hg.

Of the 17 incidents associated with underpressurization, 10 were caused by sudden depressurization, 2 resulted from kinks in the hose between the tourniquet controller and cuff, and 5 were caused by other factors. Of the incidents associated with sudden depressurization of the tourniquet cuff, 6 cases were a result of leaks in the cuff, hose, or hose connector at the cuff or controller. This caused rapid depletion of the gas reservoir and sudden depressurization during the surgical procedure. In 3 cases, sudden depressurization was caused by cuff failure. In 2 of these, the cuff "telescoped" down the limb; in the other case, the envelope of the cuff ruptured, releasing the bladder. The tenth sudden depressurization incident was due to the tubing between the tourniquet controller and cuff being disconnected when someone tripped on the hose.

In most of these cases of sudden depressurization, blood entered the surgical site, and the surgical procedure had to be suspended, the gas reservoir refilled, the cause of the leak found, and the limb re-exsanguinated. In one case, the same limb was re-exsanguinated twice. In two cases, kinking of the single hose between the tourniquet cuff and controller was detected only when the cuff could not be deflated at the end of the procedure. This resulted in a complete lack of pressure regulation at the tourniquet cuff. Similar kinking may be responsible for other reported cases of underpressurization because in such instances the tourniquet controller appears to be functioning normally. Five other incidents associated with underpressurization were attributed to a variety of causes, primarily inappropriate cuff characteristics or the physiologic status of the patient.

Of the 28 incidents associated with soft tissue injuries, 12 involved upper limbs and 16 involved lower limbs. In most cases, these soft tissue injuries were relatively minor and were resolved within a few days. The most frequently seen soft tissue injuries were bruising and blistering, particularly at the distal cuff edge; pinching underneath the cuff; and postoperative swell-

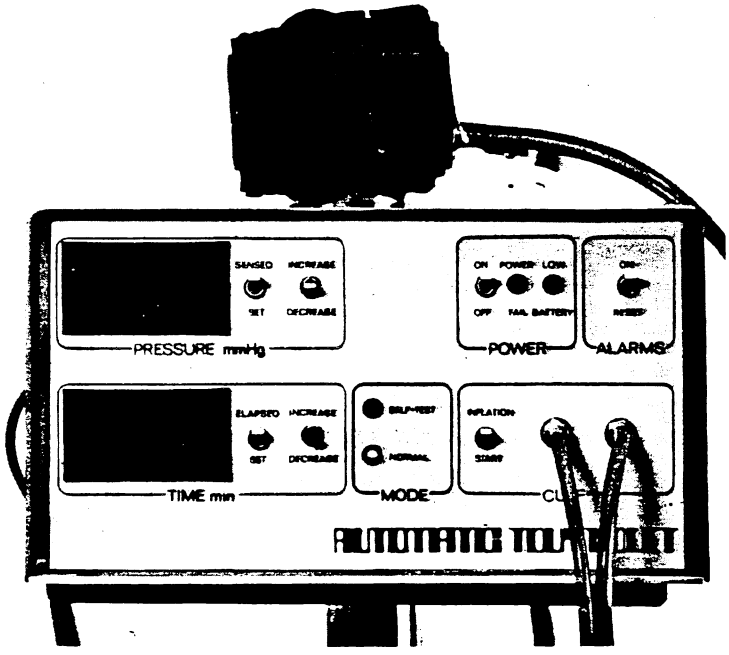

Fig 2. Experimental prototype of automated, microprocessor-based surgical tourniquet.

ing at the cuff site. A variety of causes appear to be involved, including: manipulation of the limb during the surgical procedure, inappropriate preoperative preparation of the limb, improper cuff application technique, and the use of an overly aggressive adhesive seal at the cuff margins.

The results of investigations of hazards and incidents indicate that the pneumatic tourniquets tested have the following undesirable characteristics:

- a mechanical pressure regulating valve that is prone to malfunction
- a pressure regulation mechanism that has sufficient hysteresis to make it hazardous during normal operation
- a reservoir of compressed Freon gas that is capable of generating a pressure more than twice the maximum safe level
- an aneroid gauge that deteriorates with use and provides inherently inaccurate indications of cuff pressure
- a lack of audio or visual alarms to alert the staff in the event of overpressurization, underpressurization, or other hazardous conditions such as excessive periods of application
- the lack of a fail-safe mechanism to limit the maximum pressure in the cuff to a safe level.

Despite these clearly undesirable characteristics, these pneumatic tourniquets and other types of pneumatic tourniquets with similar characteristics are widely used. Modification of such devices to achieve a desired level of safety, accuracy, and reliability and to reduce their labor-intensiveness is not feasible.

In view of the hazards and incidents investigated, a microprocessor-based tourniquet, such as the one that has recently become available, appears to have significant advantages. A preproduction model of this device, based on the experimental prototype shown in Figure 2, has been technically and clinically evaluated and employed in 54 surgical procedures to date at Vancouver General Hospital. The new device does not require compressed gas; regulates

Alarms warn of hazardous pressurization or periods of inflation.

pressure to within 2 mm Hg; and contains audiovisual alarms to warn of hazardous overpressurization, underpressurization, and excessive periods of inflation. The tourniquet automatically detects and warns of kinks in the hosing to the cuff, and an internal self-diagnostic system immediately warns of a variety of potential problems with its pressure regulation, pressure sensing alarms, and internal circuitry. The diagnostic system operates not only at start-up but also during use.

A microprocessor-based tourniquet could have eliminated or immediately detected and warned of all of the hazardous malfunctions summarized in items 1 to 6 of Table 2. Also, this tourniquet would likely have eliminated, or immediately detected and warned of, all of the malfunctions that led to the hazardous overpressurization incidents described. Similarly, at least nine (53%) of the underpressurization incidents could have been prevented through the use of the microprocessor-based device. Most of the other underpressurization incidents could have been prevented by improvements in cuff design and implementation of a cuff inspection program.

In addition to significant advances in safety and performance, the routine use of a microprocessor-based tourniquet in surgery could result in considerable cost reductions or cost containment. For example, the cost of compressed gas for a Kidde pneumatic tourniquet, the one most commonly used at present, can be estimated to be $637 per year. This is based on a projected daily use in five procedures for 250 days per year, with a new gas container costing $3.57 required every 7 cases for a tourniquet system having moderate leaks. The new tourniquet does not require compressed gas. In addition, our annual repair and testing costs per conventional tourniquet were $127. Finally, implementing published recommendations for daily checks of tourniquet calibration, more rigorous monthly performance assurance tests, and manual monitoring and controlling of tourniquet function at five-minute intervals during surgery would require approximately 10% to 15% of the time of an operating room nurse or technician.[6] This cost can be estimated at $1,950, including benefits.

A microprocessor-based tourniquet should require only annual testing, and the improved performance and alarms should eliminate the need for constant monitoring and manual control. Considering only the savings from elimination of compressed gas, a microprocessor-based tourniquet priced at $3,700 could be recovered in less than six years, with net savings thereafter. Considering compressed gas savings and reduced labor costs, and based on the assumption that time saved can be used productively elsewhere, the capital cost of a microprocessor-based tourniquet could

be recovered in about 18 months.

In summary, the advent of the microprocessor-based tourniquet is an excellent example of how a new medical device can be developed in response to a need. Routine use of such tourniquets should lead to a significant reduction in the nature and extent of the hazards associated with the use of pneumatic tourniquets in surgery. The new type of tourniquet should also facilitate further advances, such as improvements in cuff design and the development of more sophisticated devices with even better performance. Moreover, this potential increase in safety and reduction of legal liability should be achieved at a lower net cost through reductions in the supply and labor costs now associated with tourniquet use. □

Notes

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Film review: Potential Electrical Hazards in the OR

Potential Electrical Hazards in the OR is a 20-minute film authored by M Joyce Brandner, RN, in 1973. The use of electrical devices in the operating room is increasing daily. Therefore, to maintain patient safety, the perioperative nurse must be cognizant of potential electrical disasters. This film emphasizes the need for continuous education to prevent potential problems.

In stressing the vulnerability of the surgical patient to electrical injuries, the film shows the need for constant surveillance and understanding of electrical equipment by OR personnel. The author systematically provides information to assist OR nurses in decreasing electrical hazards. Topics include associations that distribute manuals on safety codes and regulations, factors relating to problems of electrical hazards, electrical current, the electrically sensitive patient, and electrical burns. The film concludes with a series of dos and don'ts of electrical safety.

Although the film does not provide an indepth study of electricity or the potential hazards that exist when using electrosurgical equipment, it is a useful introduction to electrosurgery safety for inexperienced nurses, or a supplement to a program presentation.

The presentation is available from Davis + Geck Film and Videocassette Library, 1 Casper St, Danbury, Conn 06810. The 16 mm film may be rented for $15 or the videotape version in 3/4 in U-matic format may be purchased for $100.

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