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Adverse Events of Sutures: Possible Interactions of Biomaterials?

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Abstract: Absorbable sutures are in use for more than 30 years. Tissue reactions which might be associated with suture material have rarely been reported in the past. After a long period without complications caused by suture material we observed 12 cases of unexpected tissue reactions after clean operations. Our patients 3-8 weeks after uneventful elective clean operations (varicose vein, hernia, benign soft tissue tumor) had unexpected tissue reactions (inflammation, granuloma, extrusion, fistula, abscess) in the vicinity of Vicryl®, suture material (8 cases with Vicryl®, 4 cases with Vicryl plus®). After removal of the suture material and the granulomatous tissue wounds healed without any further disturbance. These tissue reactions have been observed in patients with subcuticular sutures as well as in patients with deeper located vein ligatures. It is well known that next to patient-associated and surgeon-related factors biomaterials might have an impact on post-operative inflammatory process and healing. We use Vicryl®, suture material for ambulatory surgery since 1999 and did not see complications for a long period up to now. 11 of the patients were observed within several weeks in summer 2005, whereas only one patient has been observed in the year 2004. All 11 patients observed in 2005 had a combination of Vicryl®/ Vicryl plus® suture material in deep/subcutaneous and Dermabond® glue for skin closure.

We do not know the cause for this change. For clarification evaluation of the tissue reactions of these biomaterials including possible interactions or combined reactions should be done.

Key words: Surgical Wounds, Suture Material, Glue

Introduction

Absorbable suture material, e.g., polyglactin 910 (Vicryl®) has been used in many operative procedures in general surgery, gynecology, neurosurgery, eye surgery, dermatology, orthopedic surgery (Laufman and Rubel 1977). Vicryl® is considered a safe, non-toxic, non-immunogenic product. It became available as uncoated and coated polyglactin 910 (Blaydes and Berry 1980; Conn and Beal 1980) and more recently as coated polyglactin 910 with triclosan (Vicryl plus®) (Barbolt 2002).

Recently, we have observed within some months 12 cases of unexpected tissue reactions after clean operations (hernia, varicose vein, soft tissue tumor), in which we used Vicryl®/Vicryl plus® for subcutaneous suture. We present the clinical data and the discussion of possible causes.

Results

In 12 patients (1 – 12, tables 1 and 2), four females and eight males, 12 – 68 years old, we observed an unusual tissue reaction in the vicinity of subcutaneous sutures or varicose vein ligatures (tables 1 and 2).

Varicose Vein Surgery

In six out of these 12 patients (1, 2, 3, 9, 11, 12) who were admitted for varicose vein surgery (ligation of the sapheno-femoral or sapheno-popliteal junction, greater or lesser saphenous stripping, dissection of perforator vein), Vicryl®/Vicryl plus® 2/0 has been used for ligation of the greater saphenous vein or a perforating vein and a running subcuticular suture after ligation of the sapheno-popliteal junction followed by Dermabond® (2-octyl-cyanoacrylat) skin closure. These patients had further incisions without Vicryl®/Vicryl plus® sutures, which healed uneventful.

Two patients (2,11) with ligature of the vein developed fistula which healed when the suture material was removed.

Two patients (9, 12) with running subcuticular sutures developed a subcutaneous infection and were treated by removal of the suture material, cleansing the wound. After that the wound healed uneventful.

In two patients (1, 3) with ligature of the distal varicose vein a suture granuloma developed. It has been removed in patient 1. Patient 3 had minor complaints and did not want to have the granuloma removed.

Surgery of a Soft Tissue Tumor

In four (4, 6, 7, 8) out of the 12 patients benign soft tissue tumors of the skin or subcutaneous tissue were removed. The incision has been closed with sucutaneous suture and Dermabond®. All wounds showed an inflammatory reaction followed by extrusion of the

Table 1. Clinical data of the 12 patients presented.

No.	Gender	Patient	Age	Diagnosis	Operation	Date of operation
1	F	A.I.	40	Varicose veins	Phlebectomy	21.06.04
2	F	T.M.	53	Varicose veins	Phlebectomy	28.02.05 / 07.07.05
3	M	E.U.	65	Varicose veins	Phlebectomy	11.04.05
4	M	B. R.	68	Soft tissue tumor	Excision	20.04.05
5	M	H.T.	12	Ventral hernia	Herniotomy	28.04.05
6	M	H.E.	60	Soft tissue tumor	Excision	03.05.05
7	M	J.W.	64	Soft tissue tumor	Excision	04.05.05
8	M	B.K.	61	Soft tissue tumor	Excision	19.05.05
9	M	B.H.	65	Varicose veins	Phlebectomy	05.09.05
10	M	R.G.	54	Inguinal hernia	Herniotomy	05.09.05
11	F	B.B.	65	Varicose veins	Phlebectomy	06.09.05
12	F	K.I.	35	Varicose veins	Phlebectomy	19.09.05

Table 2. Adverse reactions in the 12 patients reported.

Pat no	Suture material in deep/subcutaneous 2/0	Skin closure with Dermabond®	Extrusion, rejection	Granuloma	Inflammation	Delayed wound - healing	Infection	Fistula	Time operation to adverse event in weeks
1	Vicryl®	∅	+	+	+	+	∅	∅	8
2	Vicryl®	+	+	+	+	+	∅	+	3
3	Vicryl®	+	+	+	+	∅	∅	∅	4
4	Vicryl®	+	+	+	+	+	∅	∅	3
5	Vicryl®	+	+	+	+	+	∅	∅	8
6	Vicryl®	+	+	∅	∅	∅	∅	∅	4
7	Vicryl®	+	+	+	+	+	∅	∅	4
8	Vicryl®	+	+	∅	+	+	∅	∅	3
9	Vicryl plus®	+	+	+	+	+	+	∅	4
10	Vicryl plus®	+	+	+	+	∅	∅	∅	4
11	Vicryl plus®	+	+	+	+	+	∅	+	4
12	Vicryl plus®	+	+	∅	+	+	+	∅	4

suture material. After extrusion or excision of the suture material the follow-up was uneventful.

Hernia Repair

One patient (5) who had a small ventral hernia repaired by open suture technique - Prolene® (polypropylene) has been used for suturing the fascia, Vicryl® for subcutaneous suture and Dermabond® for skin closure - demonstrated an inflammatory dehiscence of the wound. After removal of the Vicryl® suture material and granulomatous tissue around the suture material the wound was closed and healed without any further disturbance.

Another patient (10) had an inguinal hernia repair (modified Lichtenstein with subcuticular Vicryl plus®suture and Dermabond® skin closure) and complained about extrusion of suture material. After spontaneous extrusion of the suture the wound healed without any disturbance.

Time Course

The tissue reactions (granuloma formation, extrusion, inflammation, dehiscence, fistula formation, infection) all occurred three to eight weeks after the operative procedure within the vicinity of absorbable suture material Vicryl®/Vicryl plus®. When focus elimination - removal of the Vicryl®/Vicryl plus® sutures - has been performed, all wounds healed uneventfully (Table 2).

Discussion

We present data of 12 patients who three to eight weeks after elective clean operations developed a mild to moderate local inflammation in the vicinity of Vicryl®/Vicryl plus® suture material or fistula/infection which had to be treated surgically. 11 of the patients were observed within some weeks in summer 2005, whereas only one patient has been recognized in

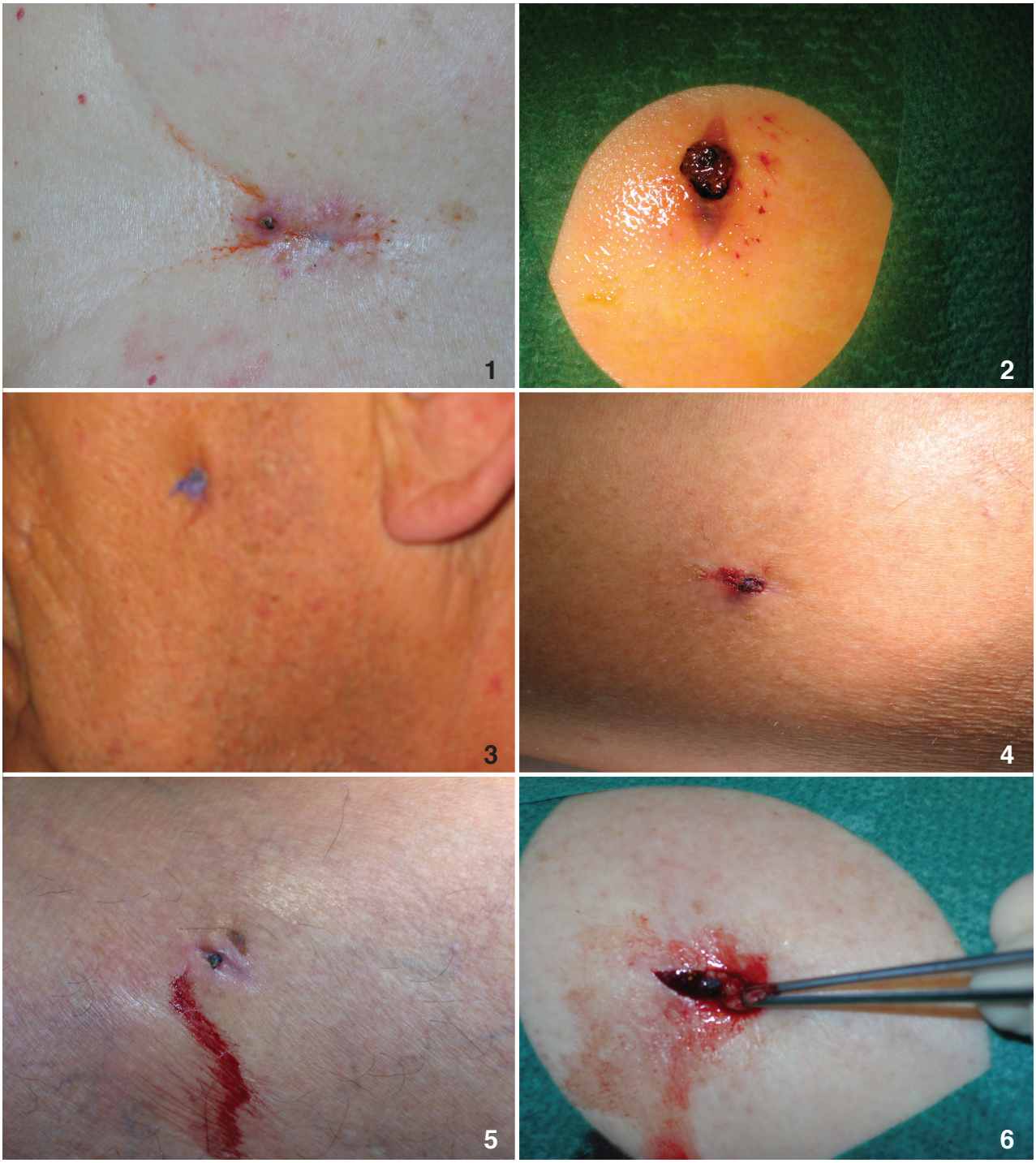

Fig. 1. Patient 4, female, 68 years old, 3 weeks after excision of a benign soft tissue tumor, located over the sternum. Subcuticular Vicryl® suture and skin closure with Dermabond®.

Fig. 2. Patient 5, male, 12 years old, 8 weeks after open herniorrhaphy of an epigastric hernia. Subcuticular Vicryl® suture and skin closure with Dermabond®.

Fig. 3. Patient 6, male, 60 years old, 4 weeks after removal of a benign soft tissue tumor left cheek. Subcuticular Vicryl® suture and skin closure with Dermabond®

Figs. 4+5. Patient 9, male, 65 years old, 4 weeks after ligation of the right sapheno-femoral and sapheno-popliteal junction with varicose vein stripping. Subcuticular Vicryl® suture and skin closure with Dermabond®.

Fig. 6. Patient 11, female, 65 years old, 4 weeks after dissection of a perforating vein in the right lower limb. Ligation of the vein with Vicryl®, skin closure with Dermabond®.

the year 2004. We use Vicryl® suture material for ambulatory surgery since 1999.

Tissue reactivity, infection and wound dehiscence rate may be influenced by patient-related factors, e.g., diabetes, overweight, malignoma, compliance. None of these factors was relevant in our patients. None of the patients had lower limb lymph edema which is known to predispose the patient to the development of bacterial infection (Stalbow 2004). Age of the patient has been considered a risk factor for infection (Jones and Millman 1990). Gabrielli et al. (2001) observed an increased tissue reactivity and more infections in patients above 50 years. The effect of age on the tissue reaction to suture material is not yet fully understood (Mishto et al. 2003). The results reported by Gabrielli may not be applicable for comparison to our cases as values with regard to incidence, type of internal sutures and suturing technique were not reported. The study period ended 14 days after the operation; we observed the tissue reaction three to eight weeks after the operation. Whether males may have an increased risk for tissue reactivity and infection, is yet unclear (Mouzas and Yeadon 1975; Gabrielli et al. 2001; Stork et al. 2004).

In addition surgical experience and technique might have an impact on the development of infections (Holzheimer et al. 1997). Clean operations, e.g., varicose vein surgery, inguinal hernia repair, soft tissue tumor excision, are considered to have a low risk to develop a surgical site infection (1%) and only in prolonged operations the infection rate may increase (Holzheimer et al. 1990). The recorded time for these operations was below 90 minutes. Comparable tissue reactions after hernia or varicose vein operations did not occur before (Holzheimer et al. 2003; Holzheimer 2004).

The patients were all operated by the same surgeon. The preoperative skin preparation has been performed by the same staff and is in agreement with recommendations (Duron and Holzheimer 1998). Postoperative inflammatory reaction (Holzheimer and Steinmetz 2000) and acute hypersensitivity to suture material (Perez et al. 1995) are seen within 48 hours after the operation. Infections which may be caused by intraoperative contamination are diagnosed in the majority of cases within the first 14 days after the operation. The incubation period of staphylococcal wound infections is usually 4 – 6 days and these infections tend to be localized (Cruse 1988). At our institution patients are seen the day after the operation and after 10 days. They are instructed to contact us in case of any inflammatory reaction of the skin.

Tissue reactions to absorbable suture material are rarely reported in the past (Farrar and Binns 1997). This might be influenced by the facts, that most surgeons don't see their patients long enough or reactions to sutures are interpreted as non-specific surgical complication (Perez et al. 1995). On the other hand, implants frequently may cause acute or chronic inflammation resulting in tissue damage and rejection. Inflammation usually occurs at the biomaterial-tissue interface and reflects the absorption of the tissue. When the biomaterial is degraded components may leach into the surrounding tissue (Griffiths et al. 1996). Larger sutures may incite greater tissue reactions (Beauchamp et al. 1988). The presence of suture material in contaminated wounds increases the incidence of infection (Paterson-Brown et al. 1987; Mehta et al. 1996). Knote and Bohnert reported on the successful use of polyglactin 910 in subcuticular sutures (1978). Continuous subcuticular suture has been favoured by some authors when compared to percutaneous skin sutures (Stillman et al. 1980). However, with regard to Vicryl® there are conflicting results after subcuticular sutures (Rosen and Carlton 1997; Shetty et al. 2004; Buchweitz et al. 2005). It is unclear, however, whether Dermabond® may cause the tissue reactions observed in our patients as indicated in other patients (Switzer et al. 2003).

Inflammatory nodules with an increased foreign body reaction have been observed in patients after injection of atoxic and nonimmunogenic material. The inflammatory nodules were likely caused by a low-grade infection within a biofilm surrounding the biomaterial (Christensen et al. 2005). Foreign body granulomas are likely to be caused by sutures (Luijendijk et al. 1994), even by infected suture material (Kise et al. 1999), or may mimick an infection (Sayegh et al. 2003). Significant infection may occur when only a few organisms are on a device at implantation (Merritt et al. 1999). In earlier studies, the incidence of abscess, granuloma or sinus formation in surgical wounds in which polyglactin 910 was applied, was higher (11.3%) when compared to polyglycolic acid (6.5 %) (Gammelgaard and Jensen 1983). In four patients out of the 12 patients we used coated polyglactin 910 with triclosan (Barbolt 2002), which has obviously not prevented the development of a local infection.

In other patients polyglactin 910 induced more fibrotic adhesions in the early postoperative period than polypropylene (Baykal et al. 2000). In animals it has been demonstrated that Vicryl® may elicit a greater acute and chronic inflammation (Formicola et al. 1980; Sanz et al. 1988). Fistula formation may be produced by fibrous reaction, intra- or postoperative contamination or suture material (Sergeant and Derom 1978). The urethrocutaneous fistula rate was significantly higher (16.6%) in the Vicryl® group compared to the polydioxanone (PDS) group (Ulman et al. 1997).

Coated Vicryl® sutures had a higher cumulative incidence of suture extrusion than that of polysorb sutures (31% versus 19%). The volume of suture material in the wound is obviously a critical determinant of suture extrusion (Drake et al. 2004).

An inflammatory reaction occuring three weeks after the procedure and later might be caused by a delayed type of hypersensitivity reaction (Farrar and Binns 1997). Sullivan et al. (1994) reported six cases of sterile ocular inflammatory reactions to monofilament suture material.

Similar reactions were observed by other authors (Nielsen et al. 1980). Delayed hypersensitivity has been reported to be caused by suture material (Della Torre et al. 2005; Dagregorio and Guillet 2004; Hausen 2003; Sanchez-Morrillas et al. 2003). A higher level of residual wound inflammation in the polyglactin 910 group has been observed after carpal tunnel decom-

pression (Erel et al. 2001). Whether leachables from biodegradable material, e.g. Dermabond®, interfered with wound healing or degradation of polyglactin 910 in our patients is not clear, and may deserve further investigations (Kobayashi et al. 1992; Switzer et al. 2003). Kobayashi reported severe inflammation in the rabbit cornea caused by 2-cyano-acrylate. Switzer has seen an increase in wound complications when Dermabond® was used.

All 11 patients observed in 2005 had a combination of Vicryl®/Vicryl plus® suture material in deep/subcutaneous and Dermabond® glue for skin closure.

The subcuticular technique itself may not be responsible for the tissue reaction (Austin et al. 1995) as we demonstrated tissue reaction, e.g., fistula, in deeper sutures. The impact of even microscopic foreign debris on post-surgical complications (Truscott 2004) and the biomaterial-mediated foreign body reactions (Hu et al. 2001; Tang et al. 1998) have been recognized and reviewed. Fibrin(ogen) seems to play a major role (Tang and Eaton 1993). These and other factor should be mentioned when choosing an appropriate suture for wound closure and healing (Spotnitz et al. 1997).

Conclusions

After a long period without complications caused by suture material we observed 12 cases (1 in 2004, 11 in 2005) of unexpected tissue reactions after clean operations (hernia, varicose vein, soft tissue tumor). All 11 patients in 2005 had a combination of Vicryl®/Vicryl plus® suture material in deep/subcutaneous and Dermabond® glue for skin closure.

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