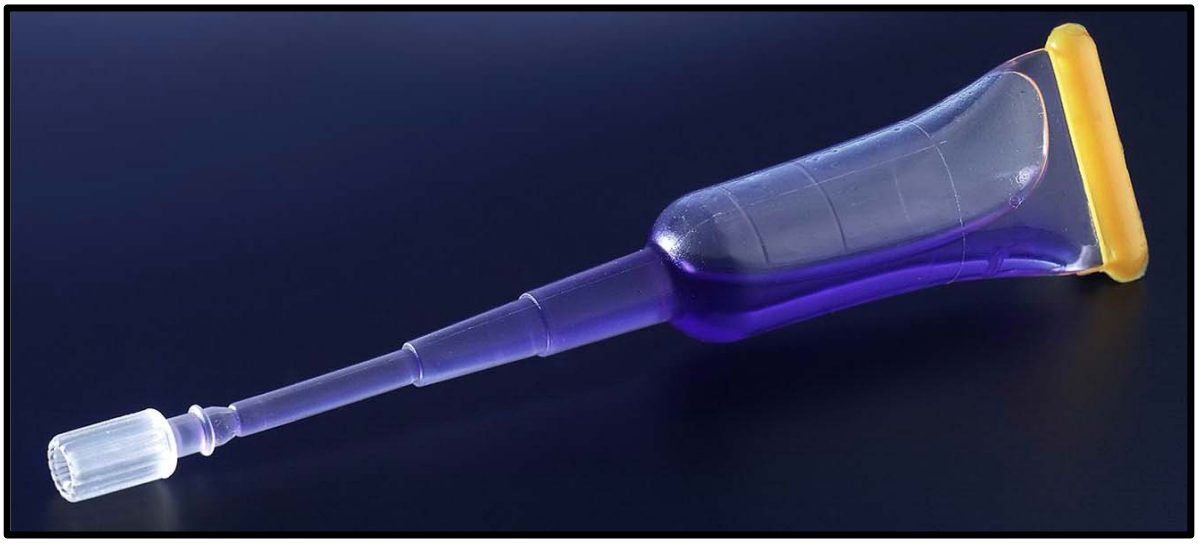
# B.Braun Biosurgicals

## Histoacryl®

## Selected Abstracts





Aesculap AG & Co. KG
Tuttlingen, Germany

## Abstracts referring to closure of skin wounds

J Paediatr Child Health. 1998 Dec;34(6):548-50.

**Randomised trial of Histoacryl blue tissue adhesive glue versus suturing in the repair of paediatric lacerations.**

Barnett P, Jarman FC, Goodge J, Silk G, Aickin R.

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OBJECTIVE: To compare Histoacryl blue tissue adhesive glue with suturing in the repair of simple paediatric lacerations. METHODOLOGY: Prospective, randomised controlled trial in tertiary paediatric emergency department. Children 4 years old or older with non-ragged lacerations <5 cm in length, <12-h-old and not involving eyelid or mucous membrane. A total of 163 patients were randomly allocated to either glue (83 cases) or sutures (80 controls) to repair their laceration. Primary outcome measures were cosmetic outcome at 3 and 12 months with secondary outcomes-length of time to perform procedure, and pain assessment of procedure by doctor, nurse, parent and child. RESULTS: Cases and controls were similar in age, wound length and width and body part involved, but more females received glue (P = 0.013). Time taken to repair the wound was faster in the glue group (median 0-2 mins vs. 6-10 min suture, P<0.001). Doctors (P = 0.02), nurses (P<0.01) and parents (P = 0.02) but not the children themselves (P = 0.24) rated glue repair as less distressing. Complications at 1 week (wound dehiscence, redness and discharge) were the same for both groups (P>0.2). Cosmetic outcome was the same for both groups at 3 (n = 65) and 12 (n = 65) months (P>0.7). CONCLUSION: Tissue adhesive glue is faster and probably less painful than suturing. Tissue adhesive glue has the same cosmetic result as suturing when used for the repair of simple lacerations in children.

Publication Types:
Clinical Trial
Comparative Study
Randomized Controlled Trial
Research Support, Non-U.S. Gov't

PMID: 9928648 [PubMed - indexed for MEDLINE]

Pediatrics. 1996 Oct;98(4 Pt 1):673-5.

**Laceration repair using a tissue adhesive in a children's emergency department.**

Bruns TB, Simon HK, McLario DJ, Sullivan KM, Wood RJ, Anand KJ.

Department of Pediatrics, Egleston Children's Hospital, Emory University School of Medicine, Atlanta, USA.

OBJECTIVE: To determine the effectiveness of a tissue adhesive, Histoacryl Blue (HAB), for laceration repair in children. DESIGN: Prospective, randomized clinical trial. SETTING: A tertiary care pediatric emergency center at Egleston Children's Hospital. PARTICIPANTS: Children who presented for laceration repair between October 1994 and February 1995 were prospectively evaluated. Patients less than 1 or greater than 18 years of age, those with lacerations greater than 5 cm, and those with lacerations located on the eyelids, ears, nose, lips, hands, feet, joints, or perineum were excluded. INTERVENTIONS: Following consent and routine wound management, including subcutaneous closure when deemed necessary, patients were randomized to receive skin sutures or HAB for cutaneous closure. METHODS: Length of time required for laceration repair was recorded. Parental perception of the pain experienced by their child was assessed using a visual analogue scale. Photographic documentation of scar appearance at the 2-month follow-up visit was evaluated by plastic surgeons using a visual analogue scale. RESULTS: Sixty-one children were enrolled: HAB group (N = 30), suture group (N = 31). No differences occurred between groups in laceration length, depth, location, or patient demographics. Length of time required for repair was decreased (median, HAB 7 minutes vs suture 17.0 minutes) and parental assessment of their child's pain was significantly less in the HAB group. Parents were more likely to recommend HAB over suturing to other parents or guardians. Cosmetic outcome in the HAB group was assessed to be as good as, or better than, the cosmetic outcome in the suture group as evaluated by two plastic surgeons. CONCLUSION: The use of HAB for laceration repair is an acceptable alternative to conventional suturing with a comparable cosmetic outcome. Advantages include less pain to the child, no need for suture removal, and more efficient use of physician time. Parents were also more likely to recommend HAB over suturing for laceration repair.

Publication Types:
Clinical Trial
Comparative Study
Randomized Controlled Trial

PMID: 8885944 [PubMed - indexed for MEDLINE]

J Paediatr Child Health. 1997 Dec;33(6):515-6.

**A prospective randomized study of wound approximation with tissue glue in circumcision in children.**

Cheng W, Saing H.

Department of Surgery, University of Hong Kong, Duchess of Kent Children's Hospital, Sandy Bay, Hong Kong.

OBJECTIVE: Bleeding and wound infection are the most common complications of circumcision. Cyanoacrylate tissue glue has been claimed to have the advantage of being haemostatic, bacteriostatic and easy to use. The purpose of this study is to assess the feasibility of using the tissue glue in approximation of circumcision wound in children. METHODOLOGY: A prospective randomized trial was carried out on 86 boys consecutively admitted into the Duchess of Kent Children's Hospital, Hong Kong. The results of wound approximation with cyanoacrylate tissue glue and suturing with interrupted 4/0 plain catgut were compared. The operations were carried out by the same surgeon using identical technique except for the wound approximation. The wound was assessed 1 day, 2 days, 3 days, 1 week and 1 month postoperatively. RESULTS: There was no statistically significant difference between the two groups in the rates of wound inflammation, infection, bleeding, dehiscence and cosmetic appearance, but the duration of operation was longer using tissue glue (19.8 min vs 16.5 min, P = 0.002). CONCLUSIONS: We conclude that tissue glue approximation of circumcision wounds in children is a feasible alternative, but it offers no extra advantage when compared to suturing.

Publication Types:
Clinical Trial
Comparative Study
Randomized Controlled Trial

PMID: 9484683 [PubMed - indexed for MEDLINE]

Cochrane Database Syst Rev. 2004;(2):CD004287.

**Tissue adhesives for closure of surgical incisions.**

Coulthard P, Worthington H, Esposito M, Elst M, Waes OJ.

Oral and Maxillofacial Surgery, University Dental Hospital of Manchester, Higher Cambridge Street, Manchester, UK, M15 6FH.

BACKGROUND: Sutures, staples and adhesive tapes are the traditional methods of wound closure, whilst tissue adhesives have entered clinical practice more recently. Closure of wounds with sutures enables meticulous closure, but sutures may induce tissue reactivity and they usually require removal. Tissue adhesives offer the advantages there are no sutures to remove later for the patient and no risk of needlestick injury to the surgeon. Tissue adhesives have been used primarily in emergency rooms but this review looks at the use of tissue adhesives in the operating room where surgeons are increasingly using these for the closure of surgical skin incisions. OBJECTIVES: To determine the relative effects of various tissue adhesives and conventional skin closure techniques on the healing of surgical wounds. SEARCH STRATEGY: The Cochrane Wounds Group Specialised Trials Register, The Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and EMBASE were searched. Bibliographies of review articles were checked for studies outside the handsearched journals and wound care product manufacturers were contacted. SELECTION CRITERIA: Randomised controlled clinical trials only. DATA COLLECTION AND ANALYSIS: Screening of eligible studies and data extraction was conducted independently and in triplicate whilst assessment of the methodological quality of the trials was conducted independently and in duplicate. Results were expressed as random effect models using weighted mean differences for continuous outcomes and relative risk with 95% confidence intervals for dichotomous outcomes. Heterogeneity was investigated including both clinical and methodological factors. MAIN RESULTS: Eight RCTs were included (630 patients). No statistically significant differences were found between various tissue adhesives and sutures (8 trials) for dehiscence, infection, satisfaction with cosmetic appearance when assessed by patients' or surgeons' general satisfaction. Nor were differences found between a tissue adhesive and tapes (2 trials) for infection, patients' assessment of cosmetic appearance, patient satisfaction or surgeon satisfaction. However a statistically significant difference was found for surgeons' assessment of cosmetic appearance with mean difference 13 (95%CI 5 to 21), the higher mean rating for the tissue adhesive group. REVIEWERS' CONCLUSIONS: Surgeons may consider the use of tissue adhesives as an alternative to sutures or adhesive tape for the closure of incisions in the operating room. There is a need for trials in all areas but in particular to include patients that require incision closure in areas of high tension and patients of general health that may impair wound healing.

PMID: 15106245 [PubMed - indexed for MEDLINE]

J Pediatr Surg. 1995 Jun;30(6):837-8.

**Use of tissue adhesive in the closure of small incisions and lacerations.**

Elmasalme FN, Matbouli SA, Zuberi MS.

Department of Pediatric Surgery, Maternity and Children Hospital, Jeddah, Saudi Arabia.

Over the last 10 years, in the operating rooms of Maternity and Children Hospital, Jeddah, more than 3,200 surgical incisions of skin made for minor surgical operations were closed without suturing by using tissue adhesive Histoacryl Blue. In addition to this, in the emergency rooms over 2,600 small lacerations of skin on various parts of the body were also repaired by the same technique. The method has certain distinct advantages over conventional suturing. The success rate was very high.

PMID: 7666319 [PubMed - indexed for MEDLINE]

1: Cochrane Database Syst Rev. 2002;(3):CD003326.

**Tissue adhesives for traumatic lacerations in children and adults.**

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BACKGROUND: Tissue adhesives have been used for many years to close simple lacerations as an alternative to standard wound closure (sutures, staples, adhesive strips). They offer many potential advantages over standard wound closure, including ease of use, decrease in pain and time to apply, as well as not requiring a follow-up visit for removal. Many studies have compared tissue adhesives and standard wound closure to determine the cosmetic outcome as well as these other secondary outcomes in their respective study populations. However, due to the wide variation in study parameters, there are no generalisable, definitive answers about the effectiveness of tissue adhesives. No study has been adequately powered to assess differences in complications, which are rare. OBJECTIVES: To summarize the best available evidence for the effect of tissue adhesives in the management of traumatic lacerations in children and adults. SEARCH STRATEGY: We searched the Cochrane Controlled Trials Register (CD ROM 2001 Issue 4), the Cochrane Wounds Group Specialized Trials Register (Nov 2001), MEDLINE (1966 to Oct 1, 2001), and EMBASE (1988 to Sept 1, 2001) for relevant randomised controlled trials (RCTs). We also searched the citations of selected studies, and we contacted relevant authors and manufacturers of tissue adhesives to inquire about other published and unpublished trials. SELECTION CRITERIA: We included RCTs comparing tissue adhesives versus standard wound closure or tissue adhesive versus tissue adhesive for acute, linear, low tension, traumatic lacerations in an emergency or primary care setting. Trials evaluating tissue adhesives for surgical incisions or other types of wounds were not considered. DATA COLLECTION AND ANALYSIS: Data from eligible studies were extracted by one reviewer and checked for accuracy by a second reviewer. Two reviewers independently assessed masked copies for quality. Outcomes of cosmesis (subgroups of age, wound location and need for deep sutures), pain, procedure time, ease of use and complications were analysed separately for two comparisons: 1) tissue adhesive versus standard wound care; and 2) tissue adhesive versus tissue adhesive. MAIN RESULTS: Eight studies compared a tissue adhesive with standard wound care. No significant difference was found for cosmesis at any of the time points examined, using either Cosmetic Visual Analogue Scale (CVAS) or Wound Evaluation Score (WES). Data were only available for subgroup analysis for age; no significant differences were found. Pain scores (Parent VAS WMD -15.7 mm; 95% CI -21.9, -9.5) and procedure time (WMD -5.6 minutes; 95% CI -8.2, -3.1) significantly favoured tissue adhesives. No studies reported on ease of use. Small but statistically significant risk differences were found for dehiscence (favouring standard wound care NNH 25 95% CI 14, 100) and erythema (favouring

tissue adhesive NNH 8 95% CI 4, 100). Other complications were not significantly different between treatment groups. Only one study was identified that compared two tissue adhesives (butylcyanoacrylate (Histoacryl TM) versus octylcyanoacrylate (Dermabond TM)) for pediatric facial lacerations. No significant difference was found for cosmesis using CVAS at 1-3 months, or using WES at 5-14 days and 1-3 months. Similarly, no significant difference was found in pain, procedure time or complications. Results for ease of use were incomplete as reported. REVIEWER'S CONCLUSIONS: Tissue adhesives are an acceptable alternative to standard wound closure for repairing simple traumatic lacerations. There is no significant difference in cosmetic outcome between tissue adhesives and standard wound closure, or between different tissue adhesives. They offer the benefit of decreased procedure time and less pain, compared to standard wound closure. A small but statistically significant increased rate of dehiscence with tissue adhesives must be considered when choosing the closure method (NNH 25).

PMID: 12137689 [PubMed - indexed for MEDLINE]

Eur J Emerg Med. 2002 Jun;9(2):155-8.

**Comparison of tissue adhesive and suturing in the repair of lacerations in the emergency department.**

Göktas N, Karcioglu O, Coskun F, Karaduman S, Menderes A.

Dokuz Eylül University Medical School, Department of Emergency Medicine, Izmir, Turkey.

The objective of this study was to compare the applications of Histoacryl Blue (HAB) and suturing regarding cosmetic outcome, cost and patient and physician satisfaction in the emergency department (ED). A total of 92 consecutive adult patients with lacerations equal to or shorter than 5 cm were enrolled in the study. Patients were randomized to either HAB or suturing. Ten-day and three-month cosmetic outcomes were evaluated via visual analogue scale (VAS) by a blinded surgeon. Cosmetic outcome, cost and patient and physician satisfaction of both groups were compared. Only 52 patients completed the follow-up at three months. Twenty-eight had been repaired with sutures and 24 with HAB. The differences regarding ten-day and three-month cosmetic outcome scales between the patients repaired with HAB and sutures were not statistically significant. Application of HAB resulted in greater satisfaction of the patient and the physician (p=0.007 and p=0.0001, respectively). Costs of HAB were significantly lower than sutures (p=0.0001). It is concluded that HAB is a cheaper method of laceration repair and results in greater satisfaction of both patients and physicians, while cosmetic outcomes were comparable. These results suggest that HAB is a viable alternative to suturing for selected lacerations in the ED.

Publication Types:
Clinical Trial
Comparative Study
Randomized Controlled Trial

PMID: 12131639 [PubMed - indexed for MEDLINE]

Eur J Emerg Med. 2002 Jun;9(2):155-8.

**Comparison of tissue adhesive and suturing in the repair of lacerations in the emergency department.**

Göktas N, Karcioglu O, Coskun F, Karaduman S, Menderes A.

Dokuz Eylül University Medical School, Department of Emergency Medicine, Izmir, Turkey.

The objective of this study was to compare the applications of Histoacryl Blue (HAB) and suturing regarding cosmetic outcome, cost and patient and physician satisfaction in the emergency department (ED). A total of 92 consecutive adult patients with lacerations equal to or shorter than 5 cm were enrolled in the study. Patients were randomized to either HAB or suturing. Ten-day and three-month cosmetic outcomes were evaluated via visual analogue scale (VAS) by a blinded surgeon. Cosmetic outcome, cost and patient and physician satisfaction of both groups were compared. Only 52 patients completed the follow-up at three months. Twenty-eight had been repaired with sutures and 24 with HAB. The differences regarding ten-day and three-month cosmetic outcome scales between the patients repaired with HAB and sutures were not statistically significant. Application of HAB resulted in greater satisfaction of the patient and the physician (p=0.007 and p=0.0001, respectively). Costs of HAB were significantly lower than sutures (p=0.0001). It is concluded that HAB is a cheaper method of laceration repair and results in greater satisfaction of both patients and physicians, while cosmetic outcomes were comparable. These results suggest that HAB is a viable alternative to suturing for selected lacerations in the ED.

Publication Types:
Clinical Trial
Comparative Study
Randomized Controlled Trial

PMID: 12131639 [PubMed - indexed for MEDLINE]

Acad Emerg Med. 1999 Mar;6(3):171-7.

**A randomized, clinical trial comparing butylcyanoacrylate with octylcyanoacrylate in the management of selected pediatric facial lacerations.**

Osmond MH, Quinn JV, Sutcliffe T, Jarmuske M, Klassen TP.

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osmond@cheo.on.ca

OBJECTIVE: To compare two tissue adhesives, butylcyanoacrylate and octylcyanoacrylate, in the treatment of small (<4 cm) superficial linear traumatic facial lacerations in children. METHODS: This was a randomized, clinical trial with parallel design. 94 children <18 years of age seen in the ED of a tertiary care pediatric hospital with a facial laceration suitable for tissue adhesive closure underwent laceration closure using either butylcyanoacrylate or octylcyanoacrylate. The primary outcome was the cosmetic result at three months rated from photographs by a plastic surgeon on a visual analog scale (VAS). Secondary outcomes included the time to perform the procedure, the perceived difficulty of the procedure, the pain perceived by the patient, and a wound evaluation score at ten to 14 days and three months. RESULTS: Ninety-four patients were randomized with 47 in each group. The two groups were similar for baseline demographic and clinical characteristics. There was no difference in the three-month cosmesis VAS (median, 70.0 mm for n-butyl-2-cyanoacrylate vs 67.5 mm for octylcyanocrylate, p = 0.84). There was no difference between the groups for time to complete the procedure (p = 0.88), parent/patient-perceived pain of the procedure (p = 0.37), or physician-perceived difficulty of the procedure (p = 0.33). Similarly, there was no difference between the groups for the percentage of early (p = 0.58) or late (p = 0.71) optimal wound evaluation scores. CONCLUSIONS: In the closure of small linear pediatric facial lacerations, octylcyanoacrylate is similar to butylcyanoacrylate in ease of use and early and late cosmetic outcomes. The superior physical properties of octylcyanoacrylate appear to add little benefit to the management of these selected lacerations. Physician preference and differing costs may dictate use for these small selected lacerations.

Publication Types:
Clinical Trial
Comparative Study
Randomized Controlled Trial
Research Support, Non-U.S. Gov't

PMID: 10192666 [PubMed - indexed for MEDLINE]

J Laryngol Otol. 2001 Jul;115(7):535-40.

**Butylcyanoacrylate tissue adhesive for columellar incision closure.**

Ozturan O, Miman MC, Aktas D, Oncel S.

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Cosmetic outcome of the columellar incision closure in external rhinoplasty patients has been a subject of discussion. This study was conducted to assess whether tissue adhesives provide an alternative option for sutureless closure of columellar skin incisions for cases utilizing open technique rhinoplastic surgery. One hundred and one patients undergoing external rhinoplasty were randomized to either topical application of butylcyanoacrylate or polypropylene sutures for columellar skin closure. The majority of tension on the wound edges was taken up using 5-0 chromic catgut. Cosmetic outcomes were evaluated by two otolaryngologists independently using visual analogue and Hollander wound evaluation scales in a blinded manner. There was no statistically significant difference in cosmesis between the surgeons' evaluation scores for either type or repair of the columellar incision. Since the tissue adhesive forms its own protective barrier, post-operative care is simplified. Closure with adhesives eliminates the need for post-operative suture removal requiring an extra visit that should lead to more efficient use of physician and patient time. Butylcyanoacrylate performs cosmetically as well as standard suture closure of columellar skin incision used for external rhinoplasty.

Publication Types:
Clinical Trial
Comparative Study
Randomized Controlled Trial

PMID: 11485582 [PubMed - indexed for MEDLINE]

Ann Emerg Med. 1993 Jul;22(7):1130-5.

**A randomized, controlled trial comparing a tissue adhesive with suturing in the repair of pediatric facial lacerations.**

Quinn JV, Drzewiecki A, Li MM, Stiell IG, Sutcliffe T, Elmslie TJ, Wood WE.

Division of Emergency Medicine, University of Ottawa, Ontario, Canada.

STUDY OBJECTIVE: To compare the tissue adhesive Histoacryl Blue with suturing in the repair of pediatric facial lacerations. DESIGN: Prospective, randomized controlled trial. SETTING: Emergency department of a pediatric teaching hospital. PARTICIPANTS: Eighty-one children presenting with clean facial lacerations less than 4 cm in length and 0.5 cm in width. INTERVENTIONS: Patients were allocated randomly to have their lacerations repaired with sutures or Histoacryl Blue. RESULTS: The two groups were similar for demographic and clinical characteristics. Photographs taken at three months were rated by two plastic surgeons blinded to the method of closure. There was no difference between groups for appearance scores on a visual analog scale (60.5 mm for Histoacryl Blue versus 57.2 mm for suture, P = .45) or on a categorical scale (Histoacryl Blue versus sutures: unacceptable, 11% versus 13%; acceptable, 59% versus 71%; excellent, 30% versus 16%; P = .76). Measures of observer agreement produced Pearson correlations of .72 and .94 on the visual analog scale and kappa coefficients of .46 and .73 on the categorical scale. Histoacryl Blue was assessed as less painful on a visual analog scale (24.7 versus 43.7 mm, P < .01) and faster (7.9 versus 15.6 minutes, P < .001). CONCLUSION: Histoacryl Blue is a faster and less painful method of facial laceration repair that has cosmetic results similar to the use of sutures.

Publication Types:
Clinical Trial
Comparative Study
Randomized Controlled Trial
Research Support, Non-U.S. Gov't

PMID: 8517562 [PubMed - indexed for MEDLINE]

Pediatrics. 1997 Feb;99(2):193-5.

**Long-term appearance of lacerations repaired using a tissue adhesive.**

Simon HK, McLario DJ, Bruns TB, Zempsky WT, Wood RJ, Sullivan KM.

Department of Pediatrics, Egleston Children's Hospital, Emory University School of Medicine, Atlanta, Georgia 30322, USA.

BACKGROUND: Histoacryl Blue (HAB), a tissue adhesive, has been shown to decrease laceration repair time, cause less pain to the child, eliminate the need for suture removal, and result in a similar short-term cosmetic outcome compared with conventional suturing. Reports suggest that poor correlation can exist between the short-term and long-term cosmetic outcomes for lacerations repaired by conventional suturing. Therefore, this study compares the long-term cosmetic outcome of HAB to conventional suturing for laceration repair in children. DESIGN: Prospective, randomized clinical trial. PARTICIPANTS: Children presenting an urban pediatric emergency department for laceration repair between October 1994 and February 1995 were eligible. Patients less than 1 or more than 18 years old, those with lacerations more than 5 cm in length, or in areas of high tension or mobility were excluded. INTERVENTIONS: After routine wound management, including subcutaneous closure when deemed necessary, patients were randomized to receive skin sutures or HAB for cutaneous closure. Photographs taken at the 2-month and 1-year follow-up visits were evaluated for cosmetic appearance by two plastic surgeons blinded to the method of repair. RESULTS: Sixty-one children were enrolled: HAB (N = 30), suture (N = 31). Thirty HAB and 25 sutured patients were assessed at 2 months, while 17 HAB and 15 sutured patients were reevaluated at 1 year. Patients that followed-up at 2 months and 1 year were comparable to those with no follow-up in: treatment group (HAB vs suture), demographics, wound characteristics, and initial parental satisfaction. The two plastic surgeons graded the cosmetic appearance of the wounds repaired by HAB to be comparable to those repaired by conventional suturing at both the 2-month and 1-year follow-up. CONCLUSIONS: The use of HAB is an ideal alternative to conventional suturing for the cutaneous closure of low tension lacerations in children with a long-term cosmetic outcome comparable to conventional suturing.

Publication Types:
Clinical Trial
Comparative Study
Randomized Controlled Trial

PMID: 9024445 [PubMed - indexed for MEDLINE]

J Hand Surg [Br]. 2001 Jun;26(3):264-5.

**A single blind, prospective, randomized trial comparing n-butyl 2-cyanoacrylate tissue adhesive (Indermil) and sutures for skin closure in hand surgery.**

Sinha S, Naik M, Wright V, Timmons J, Campbell AC.

Department of Orthopaedic Surgery, Monklands Hospital, Airdrie, UK.

Fifty patients underwent a variety of hand operations and were randomized for wound closure either with tissue adhesive (Indermil) or sutures. The two treatment groups had similar demographic characteristics and similar outcomes at the 2 and 6 week postoperative assessments which were performed by a designated tissue viability nurse blinded to the method of closure. Five minor wound dehiscences occurred: three in the adhesive group and two in the suture group. No infection occurred in either group. In conclusion, the study demonstrates tissue adhesive is as effective as suture in this type of hand surgery. 

Publication Types:
Clinical Trial
Comparative Study
Randomized Controlled Trial

PMID: 11386782 [PubMed - indexed for MEDLINE]

J Pediatr Surg. 2004 Aug;39(8):1249-51.

**Adhesive bonds or percutaneous absorbable suture for closure of surgical wounds in children. Results of a prospective randomized trial.**

van den Ende ED, Vriens PW, Allema JH, Breslau PJ.

Department of Pediatric Surgery, Red Cross Hospital, The Hague, The Netherlands.

BACKGROUND: Surgeons have become increasingly interested in replacing conventional sutures by means of adhesive bonds for the closure of skin wounds. There are several advantages to the use of adhesive bonds compared with the conventional sutures. METHODS: Between January and August 2001, all the wounds in children after groin surgery were closed with an adhesive, N-butylcyanoacrylate (Indermil, Locite Corp, 's-Hertogenbosch, The Netherlands), or with a suture, polyglactin 5-0 (Vicryl), intracutaneously. Fifty Inguinal wounds were treated with Indermil and 50 with Vicryl. Wounds were evaluated for hematoma, infection, dehiscence, or formation of granuloma. A scale from 1 to 10 expressed the cosmesis by patient and surgeon. RESULTS: The most remarkable difference in wound healing was dehiscence of the wound in 26% of cases in the adhesive group and no dehiscence in the suture group. The cosmesis of the wounds was marked with an 8.6 in the suture group and in the adhesive group with a 6.8. CONCLUSIONS: Wound dehiscence was seen significantly more frequent in the patients in whom the wound was closed with N-butylcyanoacrylate. The cosmesis of wounds closed with tissue glue was significantly lower then the cosmesis after suturing. Therefore, the authors advise, on the basis of this prospective randomized trial, that surgical wounds in children should be closed with a intracutaneous absorbable suture.

Publication Types:
Clinical Trial
Comparative Study
Randomized Controlled Trial

PMID: 15300538 [PubMed - indexed for MEDLINE]

Pediatric Endosurg. 1998 Volume 2, Number 1

**Use of N-Butyl-2-Cyanoacrylate (Histoacryl®) in Closure of Thoracoscopic an Laparoscopic Surgical Wounds in Children**

Yulevich A, Cohen Z, Mares AJ

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Among the different ways to close for surgical wounds, the use of n-Butyl-2-Cyanoacrylate (Histoacryl®), is gaining popularity; it is effective, easy to use, and shows good cosmetic results. We describe our method of using Histoacryl in detail and discuss its advantages for pediatric surgery, espacially for closure of thoracoscopy wounds.

## Abstracts referring to sclerosation therapy

Notfall & Rettungsmedizin

### [Emergency Treatment of acute variceal bleeding]

Ameis D, Seitz U, Seewald S, Brand B, de Weerth A, Thonke F, Soehendra N

Bleeding from esophageal varices is the most important complication of portal hypertension in patients with liver cirrhosis and is associated with a high mortality rate. The therapeutic success depends on the emergency treatment and consecutive definitive control of bleeding in the hospital. At the emergency site vital functions are reestablished and vasoactive drugs, i. e. terlipressin or octreotide can be successfully administered. The preferred therapy to achieve permanent control of bleeding is by endoscopic intervention. Patients with acute variceal hemorrhage should therefore be immediately transferred to a hospital providing 24 hour endoscopic services. The use of a cumbersome and hazardous balloon tamponade can thus be avoided. Endoscopically, the site of bleeding can be unambigously identified and treated by rubber band ligation or injection of N-butyl-2-Cyanoacrylate glue. During endoscopy a large-channel endoscope allows removal of blood and clots from the stomach and hence provides an effective coma prophylaxis. Despite recent progress in endoscopic and medical therapy of acute variceal hemorrhage the prognosis is determined by liver function. An orthotopic liver transplantation is therefore the only therapeutic option which positively affects the prognosis of the patient.

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Endopraxis, Ausgabe 2/95

**Assistenz bei der Histoacrylklebung**

Beilenhoff U

Seit über 20 Jahren wird die Sklerosierungstherapie bei der Beahndlung der akuten Ösophagusvarizenblutung sowie der Behandlung von Ösophagusvarizen im blutungsfreien Intervall eingesetzt. Im europäischen Raum wird als Sklerosierungsmittel in der Regel Aethoxysklerol ® (Polidocanol) verwendet, das intra- und paravasal injiziert wird.

Baillieres Best Pract Res Clin Gastroenterol. 1999 Apr;13(1):85-96.

**New haemostatic techniques: Histoacryl injection, banding/endoloop ligation and haemoclipping.**

Binmoeller KF, Soehendra N.

Division of Gastroenterology, University of California Medical Center, San Diego, USA.

New endoscopic modalities for the haemostasis of upper gastrointestinal bleeding include cyanoacrylate tissue glue injection for oesophageal and gastric varices, ligation using bands and loops for variceal and non-variceal bleeding, and clips for non-variceal bleeding. These new modalities aim to improve primary and secondary haemostasis rates and the safety of endoscopic treatment. Preliminary experience using these modalities has been encouraging, but prospective randomized trials using adequate patient numbers are still needed to validate their efficacy and safety. The choice of treatment will depend on the clinical context and the anatomy of the bleeding lesion. Cyanoacrylate injection, which achieves rapid haemostasis and obliteration of the treated varix, is ideally suited to acute variceal bleeding and the obliteration of large gastric varices. Bands and loops are used in conjunction with a transparent cap attachment for the elective treatment of oesophageal varices. The clip is most effective when a vessel from a non-variceal bleeding source can be identified.

Publication Types:
Review

PMID: 11030636 [PubMed - indexed for MEDLINE]

Endoscopy. 2003 Sep;35(9):729-35.

**Endoscopic Histoacryl obliteration vs. propranolol in the prevention of esophagogastric variceal rebleeding: a randomized trial.**

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BACKGROUND AND STUDY AIMS: The obliteration of esophageal and/or gastric varices using Histoacryl is highly effective in controlling active bleeding. However, it is not known whether repeated injections are useful for the long-term eradication of esophagogastric varices. The aim of the study was to compare endoscopic Histoacryl obliteration with propranolol in the secondary prevention of esophagogastric variceal bleeding. PATIENTS AND METHODS: Between August 1995 and February 1999, 41 patients with a first bleeding from esophageal (n = 31) or gastric (n = 10) varices were included in the study. After primary hemostasis with obliteration using Histoacryl, patients were randomly allocated either to undergo complete Histoacryl obliteration of the remaining varices (group A, n = 21) or to long-term propranolol administration (group B, n = 20), for the prevention of rebleeding. RESULTS: The two groups were well matched for age, sex, etiology of cirrhosis, Child-Pugh score, renal function, and infection at the time of admission. The median follow-up was 31.9 months (4.8 - 74.7) for group A and 23.2 months (3.0 - 70.0) for group B. Initial hemostasis was achieved in 40/41 patients (97 %). No significant difference was observed between groups A and B with regard to the incidence of early rebleeding (during the first 6 weeks; 5/21 and 3/20), bleeding-related deaths by 6 weeks (3/21 and 6/20), long-term rebleeding (11/21 and 5/20), or overall number of deaths (9/21 and 9/20). The incidence of complications was higher in group A (10/21) than group B (2/20) ($P < 0.03$). CONCLUSIONS: Repeated injections of Histoacryl with the aim of eradicating esophagogastric varices are associated with more complications compared with beta-blocker administration, with similar results in terms of rebleeding rate and survival in the long term.

Publication Types:
Clinical Trial
Comparative Study
Randomized Controlled Trial

PMID: 12929019 [PubMed - indexed for MEDLINE]

Endoscopy. 1995 Jun;27(5):355-7.

**N-butyl-2-cyanoacrylate (Histoacryl) plus sclerotherapy versus sclerotherapy alone in the treatment of bleeding esophageal varices: a randomized prospective study.**

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BACKGROUND AND STUDY AIMS: N-2-cyanoacrylate (Histoacryl) and endoscopic sclerotherapy with polidocanol have both been reported to control variceal bleeding. The aim of the present study was to compare the effectiveness of the combination of Histoacryl and endoscopic sclerotherapy with polidocanol in the management of these patients regarding early rebleeding and hospital mortality rates. PATIENTS AND METHODS: One hundred twenty-six consecutive patients with variceal hemorrhage treated with injection therapy between March 1990 and July 1993 were included in this randomized prospective study. Sixty-seven patients (Group A) were treated with Histoacryl and conventional sclerotherapy with polidocanol, and 59 patients (Group B) were treated with conventional sclerotherapy with polidocanol alone. Histoacryl was injected intravariceally during the first session in the Group A patients. RESULTS: A significantly lower bleeding recurrence rate was found in Group A patients who presented with active bleeding at the first treatment session (Group A: 2 of 20, Group B: 8 of 18, $p < 0.05$). The hospital mortality was also significantly lower in these patients (Group A: 3 of 21, Group B: 9 of 18, $p < 0.05$). CONCLUSIONS: The combination of Histoacryl with conventional sclerotherapy with polidocanol in patients with esophageal bleeding who present with active bleeding, at the initial injection therapy, can improve the results of endoscopic management.

Publication Types:
Clinical Trial
Randomized Controlled Trial

PMID: 7588348 [PubMed - indexed for MEDLINE]

Can J Gastroenterol. Vol. 4, No 9

**Endoscopic Obturation of Esophageal and Gastric Varices With a Cyanoacrylic Tissue Adhesive**

Gotlib, JP

An original method of obturation of esophageal and gastric varices with a cyanoacrylic glue has been used fo nine years. This method allows treatment of gastric and very large esophageal varices, which is difficult with common endoscopic sclerotherapy, and makes hemostasis in case of acutes bleeding easier. Thereare few complications, none lethal.

Am J Gastroenterol. 2003 Sep;98(9):1982-8.

**N-2-butyl-cyanoacrylate for bleeding gastric varices: a United States pilot study and cost analysis.**

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OBJECTIVES: N-butyl-2-cyanoacrylate has been reported to be effective for bleeding varices but is not available in the United States. We report the initial US experience with cyanoacrylate in this prospective trial and evaluate its safety, efficacy, and relative costs. METHODS: Patients with active or recent gastric variceal bleeding were eligible. Cyanoacrylate therapy was performed until variceal occlusion was achieved. Rebleeding was assessed at 72 h (acute phase), 6 wk (subacute phase), and 1 yr (chronic phase). Survival was assessed at 3 months and 1 yr. Cost analysis was performed comparing the first 17 patients to historical control patients not treated with cyanoacrylate. RESULTS: A total of 44 patients were enrolled, 37 with cirrhosis and seven with noncirrhotic portal hypertension (NCPH). In cirrhotic patients, rebleeding was seen in two of 37 (5%) at 72 h, one of 30 (3%) at 6 wk, and five of 28 (18%) at 1 yr. Survival without shunt at 3 months was 30 of 34 (88%) and at 1 yr was 24 of 31 (77%). In NCPH patients, rebleeding was seen in two of seven (29%) at 72 h. These patients received definitive therapy for NCPH after diagnosis. Mortality and costs were substantially higher in the non-cyanoacrylate group. The odds of death were greater by 7-fold in the non-cyanoacrylate group than within the cyanoacrylate group (95% CI = 1.18-41.36, p = 0.0318). At 3 months, there was a 3.18-fold difference (95% CI = 1.05-9.64, p = 0.0411) in accrued costs; at 1 yr, the difference was 2.55-fold (95% CI = 0.96-6.94, p = 0.0585). The cost-effective ratio was estimated as 108,237 US dollars/death averted, reflecting marked cost reduction with improved survival in the cyanoacrylate-treated group. This is believed to result largely from avoidance of shunt interventions. CONCLUSIONS: Cyanoacrylate treatment of gastric varices is safe, clinically effective, and cost effective.

PMID: 14499775 [PubMed - indexed for MEDLINE]

Endoscopy. 2007 Jun;39(6):487-91. Epub 2007 Mar 13.

**Improvement of tissue-adhesive obliteration of bleeding gastric varices using adjuvant hypertonic glucose injection: a prospective randomized trial.**

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BACKGROUND AND STUDY AIMS: Rebleeding can occur after endoscopic injection of gastric varices with tissue adhesive. The aim of this study was to evaluate whether adjuvant hypertonic glucose solution injections enhance the effects of Histoacryl after successful initial variceal obliteration. PATIENTS AND METHODS: A total of 67 patients (37 men, 30 women; mean age +/- standard deviation [SD] 60 +/- 17 years) with initially successful Histoacryl obliteration of bleeding gastric varices were included in the study and randomly divided into two groups: a "combined" group of patients who had adjuvant injection of hypertonic glucose solutions in cases of residual gastric varices (F1 or less) and a "control" group of patients who did not receive such therapy. End points were either variceal recurrence/progression (F2 or more) requiring Histoacryl reinjection or rebleeding. RESULTS: Residual small varices were found in 56% of patients in the combined group and in 60% of patients in the control group. Adjuvant therapy was only performed in the combined group. During the follow-up period (mean duration +/- SD 37.9 +/- 18.5 months, range 19-56 months), two patients in the combined group showed gastric variceal progression, compared with nine patients showing progression in the control group, with two cases of rebleeding, both occurring in the control group. Two years after the first Histoacryl injection, the cumulative proportion of patients who did not have gastric variceal progression was significantly higher in the combined group than it was in the control group (92.8% vs. 71.4%, P = 0.029). There was no significant difference between the two groups with respect to their survival curves (P = 0.12). No marked immediate or delayed symptoms or complications were observed in the patients given hypertonic glucose injections. CONCLUSIONS: Adjuvant treatment with hypertonic glucose solution for residual small gastric varices is a safe and simple method. It helps reduce the recurrence or progression of gastric varices after tissue adhesive injections and can therefore reduce the risk of rebleeding.

Publication Types:
Randomized Controlled Trial
Research Support, Non-U.S. Gov't

PMID: 17354182 [PubMed - indexed for MEDLINE]

Hepatology. 2001 May;33(5):1060-4.

**A prospective, randomized trial of butyl cyanoacrylate injection versus band ligation in the management of bleeding gastric varices.**

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Gastric variceal bleeding is a catastrophic event. Both cyanoacrylate injection and banding ligation have been proven to be effective in the management of bleeding gastric varices. This study was performed to compare the efficacy and complications of both the modalities. Cirrhotic patients with a history of gastric variceal bleeding were randomized to 2 groups. The group receiving endoscopic obturation (group A) comprised 31 patients and the group receiving band ligation (group B) comprised 29 patients. Butyl cyanoacrylate and pneumatic-driven ligator were applied, respectively. Treatment was repeated regularly until obliteration of gastric varices. Active bleeding occurred in 15 patients in group A and 11 patients in group B. Initial hemostatic rate (defined as no bleeding for 72 hours after treatment) was 87% in group A and 45% in group B (P = .03). The sessions required to achieve variceal obliteration and obliteration rates were similar in both the groups. However, rebleeding rates were significantly higher in group B (54%) than group A (31%) (P = .0005). Treatment-induced ulcer bleeding occurred in 2 patients (7%) in group A and 8 patients (28%) in group B (P = .03). The amount of blood transfusions required were also higher in group B than group A (4.2 +/- 1.3 vs. 2.6 +/- 0.9 units, respectively) (P < .01). Nine patients of group A and 14 patients of group B died (P = .05). In conclusion, endoscopic obturation using cyanoacrylate proved more effective and safer than band ligation in the management of bleeding gastric varices.

Publication Types:
- Clinical Trial
- Comparative Study
- Randomized Controlled Trial
- Research Support, Non-U.S. Gov't

PMID: 11343232 [PubMed - indexed for MEDLINE]

Am J Gastroenterol. 2002 Apr;97(4):1010-5.

**A randomized controlled trial of cyanoacrylate versus alcohol injection in patients with isolated fundic varices.**

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OBJECTIVE: Treatment of bleeding gastric varices (GVs) is still controversial, mainly because of anecdotal studies or inclusion of patients with GVs located at different sites that have variable incidences of bleeding. A prospective study was undertaken to compare the efficacy and safety of GV sclerotherapy using alcohol and GV obturation using cyanoacrylate glue. METHODS: Thirty-seven consecutive patients with portal hypertension and endoscopic evidence of isolated GVs, 17 presenting with histories of active bleeding, were randomized to receive endoscopic intervention either with alcohol (n = 17) or with cyanoacrylate glue (n = 20) injection. Variceal obliteration, rebleeding, or death was the endpoint. RESULTS: The glue was significantly more effective in achieving variceal obliteration than alcohol (100% vs 44%, $p < 0.05$). Furthermore, this could be achieved in a significantly shorter period (2.0 +/- 1.6 vs 4.7 +/- 3.2 wk, $p < 0.05$) and with a smaller volume of the agent. Cyanoacrylate glue injection could achieve arrest of acute GV bleeding more often than alcohol (89% vs 62%), and the need for rescue surgery was less; the difference was, however, not significant. Six patients died from uncontrolled GV bleeding, four being in the alcohol group. During a mean follow-up of 15.4 +/- 3.7 months there was no recurrence of GVs in either group. CONCLUSIONS: Our results show that cyanoacrylate is more effective and achieves GV obliteration faster than injection sclerotherapy with alcohol. It also appears to be more useful in controlling acute GV bleeding, with less of a need for rescue surgery.

Publication Types:
Clinical Trial
Comparative Study
Randomized Controlled Trial

PMID: 12003381 [PubMed - indexed for MEDLINE]

Endoscopy. 2003 Feb;35(2):136-44.

**Variceal bleeding and portal hypertension: has there been any progress in the last 12 months?**

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A review of the literature on the management of esophagogastric varices published in the last 12 months shows that the data are still quite conflicting. In the primary and secondary prophylaxis of variceal bleeding, beta-blockers are still the mainstay of pharmacotherapy. Measurement of the hepatic portal venous pressure gradient is considered to be a reliable parameter for successful reduction of portal pressure using medical therapy. However, intolerance of propranolol requiring discontinuation of therapy has been observed in approximately 30 % of patients. Patients' compliance with medication may represent another drawback of medical therapy. The role of endoscopic band ligation in secondary prophylaxis is now indisputable, especially in comparison with sclerotherapy. In the primary prevention of variceal bleeding, band ligation is beginning to have a competitive edge over pharmacological therapy. Acute variceal bleeding is no longer a frequent morbid emergency. Most cases of bleeding can now be managed successfully with band ligation and N-butyl-2-cyanoacrylate obliteration. N-butyl-2-cyanoacrylate has come into increasingly widespread use in the treatment of bleeding gastric fundal varices in which surgery or transjugular intrahepatic portosystemic shunting were previously regarded as the preferred therapies.

Publication Types:
Review

PMID: 12561007 [PubMed - indexed for MEDLINE]

Endoscopy. 1987 Nov;19(6):221-4.

**N-butyl-2-cyanoacrylate: a supplement to endoscopic sclerotherapy.**

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We report on our two years' experience with the tissue adhesive n-butyl-2-cyanoacrylate. During this period 202 patients suffering from esophagogastric varices were treated endoscopically. With the aid of the tissue adhesive the conventional sclerotherapy with Polidocanol 1% has been clearly improved. Problems concerning early recurrent bleeding and fundic varices are satisfactorily solved. The endoscopic hemostasis of severe variceal bleedings has become safer and surer. The overall hospital mortality of these patients has sunk from 31.5 to 17.5%. Cyanoacrylate is a very useful substance for obliterating large esophagogastric varices. However, the complete elimination of esophageal varices, which is the guarantee for a long-term freedom from recurrent bleeding, can only be achieved by using a genuine sclerosing agent.

PMID: 3500847 [PubMed - indexed for MEDLINE]

Hepatology. 2006 Apr;43(4):690-7.

**A randomized trial of endoscopic treatment of acute gastric variceal hemorrhage: N-butyl-2-cyanoacrylate injection versus band ligation.**

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Progression of gastric variceal hemorrhage (GVH) is poorer than esophageal variceal bleeding. However, data on its optimal treatment are limited. We designed a prospective study to compare the efficacy of endoscopic band ligation (GVL) and endoscopic N-butyl-2-cyanoacrylate injection (GVO). Liver patients with cirrhosis with or without concomitant hepatocellular carcinoma (HCC) and patients presenting with acute GVH were randomized into two treatment groups. Forty-eight patients received GVL, and another 49 patients received GVO. Both treatments were equally successful in controlling active bleeding (14/15 vs. 14/15, P = 1.000). More of the patients who underwent GVL had GV rebleeding (GVL vs. GVO, 21/48 vs. 11/49; P = .044). The 2-year and 3-year cumulative rate of GV rebleeding were 63.1% and 72.3% for GVL, and 26.8% for both periods with GVO; P = .0143, log-rank test. The rebleeding risk of GVL was sustained throughout the entire follow-up period. Multivariate Cox regression indicated that concomitance with HCC (relative hazard: 2.453, 95% CI: 1.036-5.806, P = .041) and the treatment method (GVL vs. GVO, relative hazard: 2.660, 95% CI: 1.167-6.061, P = .020) were independent factors predictive of GV rebleeding. There was no difference in survival between the two groups. Severe complications attributable to these two treatments were rare. In conclusion, the efficacy of GVL to control active GVH appears not different to GVO, but GVO is associated with a lower GV rebleeding rate.

Publication Types:
Randomized Controlled Trial
Research Support, Non-U.S. Gov't

PMID: 16557539 [PubMed - indexed for MEDLINE]

Endoscopy. 1995 Jun;27(5):358-64.

**The value of combined use of N-butyl-2-cyanoacrylate and ethanolamine oleate in the management of bleeding esophagogastric varices.**

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BACKGROUND AND STUDY AIMS: Recently, tissue adhesive material has been used to improve the initial control of bleeding from huge esophagogastric varices, and to prevent them from rebleeding, in contrast to the conventional sclerotherapy. The present study assessed the value of the combined use of the tissue adhesive substance: N-butyl-2-cyanoacrylate and ethanolamine oleate 5% for management of bleeding esophagogastric varices. PATIENTS AND METHODS: One hundred and fourteen patients with documented active variceal bleeding at the time of endoscopy were alternatively randomized into two groups. The combined therapy group included 58 patients who underwent injection using both cyanoacrylate for large esophageal and gastric varices and a sclerosant agent for remaining varices. The sclerosis, or control, group included 56 patients, who underwent injection with ethanolamine oleate. RESULTS: This study proved the value of the combined therapy for the initial control of all bleeders (the follow-up period ranged from 12 to 32 months). In the sclerosis group, failure of the initial control of bleeding was reported in two cases (3.6%). Recurrent bleeding occurred in 8.6% in the combined therapy group compared to 25% in the sclerosis group ($p < 0.01$). Two months of therapy was required to achieve complete eradication of varices in 56.5% and 21.4% in the combined therapy and the sclerosis group, respectively. The mean number of sessions needed until the time of evaluation was 2.4 +/- 1.1 in the combined therapy group versus 5.1 +/- 2.3 sessions in the sclerosis group. The difference showed high statistical significance ($p < 0.01$). Minor complications occurred less frequently in the combined therapy group. Only one patient in the combined therapy group developed portal pyemia after extension of the tissue adhesive material from the site of injection into the portal vein. This patient died of hepatic failure. The mortality in the combined therapy group was lower than that in the sclerosis group (3.5% and 8.8% respectively, $p > 0.05$). CONCLUSION: The combined use of tissue adhesive and sclerosant materials seems to be the best plan for rapid eradication of esophagogastric varices within a short time, requiring the lowest number of injection sessions and involving minor complications and low mortality.

Publication Types:
Clinical Trial
Randomized Controlled Trial
PMID: 7588349 [PubMed - indexed for MEDLINE]