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·临床研究·

载药栓塞微球经肝动脉化疗栓塞联合微波消融治疗大肝癌的临床疗效

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[摘 要] **目的** 观察载药栓塞微球经肝动脉化疗栓塞(DEB-TACE)联合微波消融治疗大肝癌的临床疗效。**方法** 选取2016年10月至2017年6月于徐州医科大学附属医院就诊的原发性大肝癌患者58例作为研究对象,按治疗方法的不同分为2组,其中采用载药栓塞微球经肝动脉化疗栓塞联合微波消融治疗的32例为DEB-TACE组,经肝动脉化疗栓塞联合微波消融治疗的26例为cTACE组。分别记录2组患者治疗前、治疗后2周、4周和8周时血清甲胎蛋白(AFP)、血清白蛋白(ALB)、总胆红素(TBIL)、天门冬氨酸氨基转移酶(AST)和丙氨酸氨基转移酶(ALT)水平变化,治疗8周后对2组患者的疗效进行评价,比较2组患者的并发症以及术后1年、2年的生存情况。**结果** DEB-TACE组治疗后总有效率为84.38%,明显高于cTACE组的61.54%,差异有统计学意义($\chi^2=3.902$,$P=0.048$);2组患者治疗前血清AFP、ALT、AST、TBIL及ALB比较,差异无统计学意义($P>0.05$);治疗后2周,2组患者血清AFP、ALB与治疗前相比均明显降低,而血清ALT、AST及TBIL则明显升高,差异有统计学意义($P<0.05$);治疗后4周和8周,2组患者的血清AFP、ALT、AST、TBIL及ALB较治疗后2周明显改善,且DEB-TACE组血清AFP明显低于cTACE组,肝功能明显优于cTACE组,差异有统计学意义($P<0.05$);2组患者术后1年生存率比较,差异无统计学意义($P>0.05$),但DEB-TACE组术后2年生存率明显高于cTACE组,差异有统计学意义($P<0.05$);2组患者治疗后均出现发热、呕吐、腹痛和腹胀等常见的不良反应,其中DEB-TACE组腹痛和腹胀发生率低于cTACE组,差异有统计学意义($P<0.05$)。**结论** DEB-TACE联合微波消融治疗大肝癌的疗效和安全性均明显优于cTACE联合微波消融,且能够提高患者术后2年生存率。

[关键词] 大肝癌;载药栓塞微球;微波消融;经肝动脉化疗栓塞;原发性肝癌

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Clinical efficacy of drug-eluting beads transcatheter aterial chomoembolization combined with microwave ablation in treatment of large hepatocellular carcinoma

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Abstract: Objective To observe the clinical efficacy of drug-eluting beads transcatheter aterial chomoembolization (DEB-TACE) combined with microwave ablation in the treatment of large hepatocellular carcinoma (HCC). **Methods** Totally 58 patients with primary large hepatocellular carcinoma treated in our hospital from October 2016 to June 2017 were selected as the research objects,and they were divided into two groups according to the different methods,including 32 cases in the DEB-TACE group and 26 cases in the conventional transcatheter arterial chemoembolization group (cTACE group). Patients of the DEB-TACE group were treated by DEB-TACE combined with microwave ablation,while patients of the cTACE group were treated by cTACE combined with microwave ablation. Record the change of serum alpha-fetoprotein (AFP),serum albumin (ALB),total bilirubin (TBIL),aspertate aminotransferase (AST) and alanine aminotransferase (ALT) of the two groups before surgery and 2 weeks,4 weeks and 8 weeks after surgery. Evaluated the curative effect of patients in the two groups at 8 weeks after treatment,and compared the complications and postoperative survival situation of patients at 1 year and 2 years after treatment. **Results** The total effective rate of DEB-TACE group after treatment was 84.38%,which was significantly higher than 61.54% in the cTACE group,the difference was statistically significant ($\chi^2=3.902$,$P=0.048$). There was no significant difference in serum AFP,ALT,AST,TBIL and ALB between the two groups before treatment ($P>0.05$). Two weeks after treatment,the serum AFP and ALB of the two groups were significantly lower than those before treatment,while the serum ALT,AST and TBIL were significantly higher than those before treatment,with statistically significant difference ($P<0.05$). Four weeks and eight weeks after treatment,the serum AFP,ALT,AST,TBIL and ALB of the two groups were significantly improved compared to those at two weeks after treatment,and the serum AFP of DEB-TACE group was significantly lower than that of the cTACE group,and the liver function was significantly better than that of cTACE group,the difference was statistically significant ($P<0.05$). There was no significant difference between DEB-TACE group and cTACE group in terms of the 1-year survival rate ($P>0.05$). The 2-year survival rate of DEB-TACE group was significantly higher than that of the cTACE group ($P<0.05$). After

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treatment, patients of the two groups showed common adverse reactions such as fever, vomiting, abdominal pain and abdominal distension, among which the incidence of abdominal pain and abdominal distension in DEB-TACE group was significantly lower than those in cTACE group, with statistically significant difference ($P<0.05$). **Conclusion** DEB-TACE combined with microwave ablation is significantly better than cTACE in efficacy and safety in the treatment of large liver cancer, and it can improve the short-term survival rate of patients.

Keywords: large hepatocellular carcinoma; drug-eluting beads; microwave ablation; transcatheter arterial chemoembolization; primary hepatic carcinoma

原发性肝癌作为临床常见恶性肿瘤之一,其发病率居全部恶性肿瘤的第6位,病死率居第3位[1-2]。肝癌最为有效的治疗方式是根治性手术,但其早期症状不明显,当患者确诊时,病灶已经出现扩散,尤其是对于肝癌病灶较大、毗邻肝门和大血管、出现血管浸润等情况,其切除率极低,仅有20%~25%的肝癌患者适合手术切除[3-4]。经肝动脉化疗栓塞(transcatheter arterial chemoembolization,TACE)作为非手术姑息性治疗方式的首选,能精确栓塞肿瘤供血动脉,将抗肿瘤药物的作用发挥到最大化,且可避免过多的化疗药物暴露于全身,因此广泛应用于临床[5]。传统的经肝动脉化疗栓塞(conventional transcatheter arterial chemoembolization,cTACE)主要依靠碘油和化疗药物联合给药,其安全性已被公认,但存在一定局限,如:不能稳定肿瘤局部药物浓度,癌周侧支循环冲刷易造成碘油流失,导致肝肿瘤血供不能长时间阻断;化疗药物易流失,难以长久栓塞,进而大大增加不良反应的发生,还会降低对肿瘤的杀伤效果[6]。载药栓塞微球经肝动脉化疗栓塞(durg-eluting bead transcatheter arterial chemoembolization,DEB-TACE),不仅能够长久地栓塞肿瘤血供,还能负载抗肿瘤药物,并且能够缓慢长久释放[7]。因cTACE并不能完全杀死肿瘤细胞,且容易出现转移,目前cTACE联合微波消融是正在探索的序贯治疗方法之一。本研究将DEB-TACE和微波消融联合应用于大肝癌的治疗,并与cTACE联合微波治疗比较,以期为临床大肝癌的治疗提供参考。

1 资料与方法

1.1 临床资料

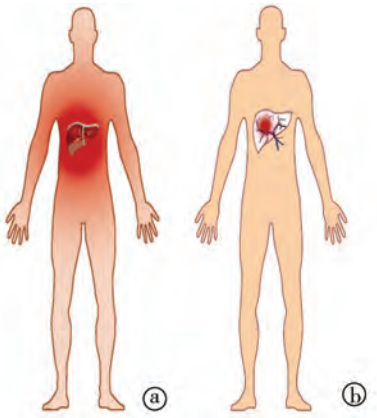
选取2016年10月至2017年6月于徐州医科大学附属医院就诊的58例原发性大肝癌患者作为研究对象,按照治疗方法的不同分为2组,32例采用DEB-TACE联合微波消融治疗的患者设为DEB-TACE组,26例采用cTACE联合微波消融治疗的患者设为cTACE组。纳入标准:①经MRI或增强CT确诊为肝癌,同时经穿刺病理诊断为肝细胞癌;②因毗邻大血管、血管浸润等无法手术切除;③肝功能属于Child A级或B级;④巴塞罗那(BCLC)分期为B期或者C期;⑤单发病灶直径>5 cm或多发最大病灶>5 cm。排除标准:①既往存在门静脉高压且致消化道出血;②伴有其他脏器转移;③存在严重凝血机制障碍,血小板低于50×10^9/L。2组患者年龄、身高、体质量、肿瘤直径等临床资料比较差异无统计学意义($P>0.05$),具有可比性(表1)。

表1 2组患者临床资料对比

项目	DEB-TACE组($n=32$)	cTACE组($n=26$)	t/χ^2	P
男/女(例)	27/5	20/6	0.518	0.472
年龄(岁)	59.25±5.67	58.95±5.71	0.200	0.842
身高(cm)	170.09±10.24	169.94±10.19	0.056	0.956
体质量(kg)	68.14±4.29	68.26±4.31	0.106	0.916
肿瘤直径(cm)	8.16±0.74	8.25±0.82	0.439	0.662
肿瘤数目(个)	1.62±0.34	1.59±0.32	0.343	0.733
肿瘤大小[例(%)]			0.131	0.718
5~10 cm	27(84.38)	21(80.77)		
>10 cm	5(15.62)	5(19.23)		
肝炎类型[例(%)]			0.114	0.736
乙型	26(81.25)	22(84.62)		
丙型	6(18.75)	4(15.38)		
Child分级[例(%)]			0.496	0.481
A级	28(87.50)	21(80.77)		
B级	4(12.50)	5(19.23)		
BCLC分期[例(%)]			0.100	0.751
B期	28(87.50)	22(84.62)		
C期	4(12.50)	4(15.38)		
AFP[例(%)]			0.006	0.941
≥400 ng/mL	20(62.50)	12(46.15)		
<400 ng/mL	16(37.50)	10(53.85)		

1.2 方法

1.2.1 TACE 常规消毒,采用Seldinger穿刺技术,行肠系膜上动脉或腹腔干造影,明确肿瘤的分布、血供以及有无静脉瘘等。在X射线透视和数字减影血管造影指导下将导管置于靶血管处,经导管注射化疗药物和栓塞剂。cTACE组注药方法:先以阿霉素碘油乳剂(含碘40%,规格为每支10 mL)栓塞肿瘤末梢血管,然后注入40~60 mg吡柔比星,最后采用明胶海绵栓塞肿瘤供血动脉近端,延长化疗时效。DEB-TACE组注药方法:将加载有60 mg吡柔比星的CalliSpheres®载药栓塞微球和对比剂混合,采用脉冲式注射进行栓塞。药物分布情况见图1。



a:cTACE;b:DEB-TACE

图 1 药物分布示意图

1.2.2 微波消融 cTACE 治疗 1~2 周后复查,患者的肝功能正常或者恢复至治疗前水平,则采取微波消融治疗。因纳入的患者病灶较大,采用双针或单针双中心微波消融。全身麻醉或局部麻醉后常规消毒,在 B 超引导下穿刺至肿瘤组织中心位置,依据肿瘤病灶形态、大小设定消融参数,选择多次叠加治疗或者多针同时多中心消融,消融过程中密切关注患者生命体征,治疗时间 5~15 min,消融范围大于影像学肿瘤边缘 0.5~1 cm,保证充分杀死肿瘤可能浸润部分,完成消融后,酌情对穿刺针道进行电凝,避免出血和转移,术后进行常规抗感染、止血和保肝等对症治疗。

1.3 观察指标

分别记录 2 组患者治疗前及治疗后 2 周、4 周、8 周时血清甲胎蛋白(alpha fetoprotein,AFP)水平和肝功能。肝功能指标包括血清白蛋白(albumin,ALB)、总胆红素(total bilirubin,TBIL)、天门冬氨酸氨基转移酶(aspartate aminotransferase,AST)、丙氨酸氨基转移酶(alanine aminotransferase,ALT)水平变化。治疗后 8 周对 2 组患者的疗效进行评价,跟踪随访 2 组患者的并发症以及术后 1 年、2 年的生存情况。随访截止时间为 2019 年 6 月。疗效评价参照实体瘤疗效评价标准(response evaluation criteria in solid tumors,RECIST)[8]:完全缓解(complete remission,CR)为肿瘤完全坏死,复查时腹部 CT 显示所有病灶动脉增强显影消失;部分缓解(partial remission,PR)为部分坏死,目标病灶直径综合缩小 30% 及以上;疾病进展(progressive disease,PD)为病灶直径增大 20% 及以上或者出现了新发病灶;疾病稳定(stable disease,SD)为速效程度未达到 PR 或者增大未达到 PD。

1.4 统计学方法

数据采用 SPSS 16.0 软件进行统计学分析,所有数据均经正态分布和方差齐性检验,其中计量资料以均数±标准差($\bar{x} \pm s$)表示,组间比较采用独立 t 检验;计数资料采用百分比(%)表示,组间比较采用 χ^2 检验,生存率采用 Kaplan-Meier 法分析,组间比较采用 Log-rank 时序检验,以 $P<0.05$ 表示差异具有统计学意义。

2 结果

2.1 2 组患者临床疗效对比

DEB-TACE 组治疗后总有效率高于 cTACE 组,差异具有统计学意义($\chi^2=3.902$,$P=0.048$),见表 2。

表 2 2 组患者临床疗效对比[例(%)]

组别	n	CR	PR	SD	PD	总有效
DEB-TACE 组	32	4(12.50)	23(71.88)	4(12.50)	1(3.13)	27(84.38)
cTACE 组	26	2(7.69)	14(53.85)	5(19.23)	1(3.85)	16(61.54)

2.2 2 组患者治疗前后血清 AFP、肝功能指标对比

2 组患者治疗前血清 AFP、ALT、AST、TBIL 和 ALB 比较差异无统计学意义($P>0.05$);治疗后 2 周,2 组患者血清 AFP、ALB 与治疗前相比均明显降低,而血清 ALT、AST 和 TBIL 均明显升高,差异具有统计学意义($P<0.05$);治疗后 4 周和 8 周,2 组患者的血清 AFP、ALT、AST、TBIL 和 ALB 较治疗后 2 周均明显改善,且 DEB-TACE 组血清 AFP 水平明显低于 cTACE 组,肝功能指标明显优于 cTACE 组,差异具有统计学意义($P<0.05$),见表 3。

表 3 2 组患者治疗前后血清 AFP、肝功能指标对比

组别	时间	AFP(ng/mL)	ALT(g/L)	AST(g/L)	TBIL(μmol/L)	ALB(g/L)
DEB-TACE 组	治疗前	487.19±54.78	43.19±4.57	43.26±4.37	22.14±2.51	38.96±3.89
($n=32$)	治疗后 2 周	208.78±23.89*	64.29±5.21*	71.52±6.78*	27.34±2.18*	33.28±3.29*
	治疗后 4 周	67.19±10.78#△	52.28±4.89#△	58.75±6.23#△	24.59±1.98#△	37.96±2.97#△
	治疗后 8 周	29.87±3.46#△	46.15±5.02#△	44.92±6.19#△	20.18±2.21#△	38.25±3.01#△
cTACE 组	治疗前	492.19±52.38	43.08±4.52	43.98±4.48	22.24±2.43	39.02±3.92
($n=26$)	治疗后 2 周	298.76±57.19*	68.27±5.33*	75.74±6.92*	32.19±3.29*	30.09±3.11*
	治疗后 4 周	124.32±10.29*#	57.74±4.92*#	63.28±6.34*#	26.78±2.19*#	33.89±2.89*#
	治疗后 8 周	50.26±4.18*#	48.26±4.94*#	50.89±6.34*#	23.48±2.68*#	35.88±3.02*#

*:与治疗前对比,$P<0.05$;#:与治疗后 2 周对比,$P<0.05$;△:与 cTACE 组比较,$P<0.05$

2.3 2组患者术后生存情况对比

2组患者术后1年生存率比较差异无统计学意义($P>0.05$);DEB-TACE组术后2年生存率明显高于cTACE组,差异具有统计学意义($P<0.05$),见表4。

表4 2组患者术后生存情况对比[例(%)]

组别	n	术后1年	术后2年
DEB-TACE组	32	26(81.25)	22(68.75)
cTACE组	26	19(73.08)	10(38.46)
χ^2		0.551	5.321
P		0.458	0.021

2.4 2组患者治疗后并发症情况对比

2组患者治疗后均出现发热、呕吐、腹痛和腹胀等常见的不良反应,其中DEB-TACE组腹痛和腹胀发生率低于cTACE组,差异具有统计学意义($P<0.05$),见表5。

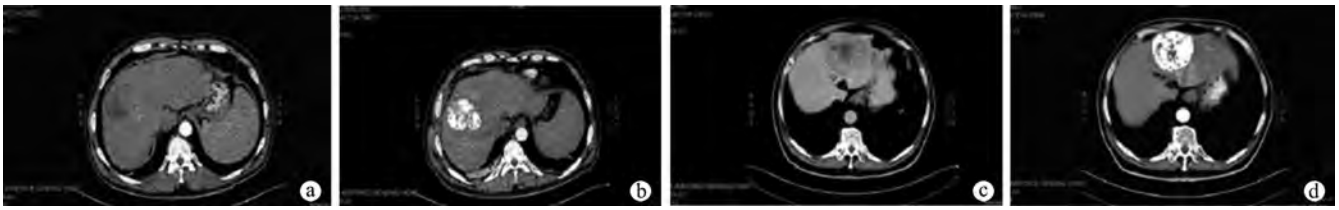
表5 2组患者治疗后并发症情况对比[例(%)]

组别	n	发热	腹痛	腹胀	呕吐
DEB-TACE组	32	10(31.25)	17(53.13)	9(28.13)	8(25.00)
cTACE组	26	12(46.15)	21(80.77)	14(53.85)	8(30.77)
χ^2		1.353	4.852	3.966	0.239
P		0.245	0.028	0.046	0.625

2.5 典型病例

病例1:患者,男,60岁。治疗前肝右叶肿瘤8.1 cm×7.6 cm,伴有门脉癌栓(图2a),DEB-TACE治疗后3个月复查增强CT,显示碘油沉积良好,未见残余病灶,无肿瘤复发(图2b)。

病例2:患者,男,61岁。治疗前左内叶巨块性肿瘤伴有门脉癌栓,最大层面8.2 cm×7.5 cm(图2c),cTACE治疗后3个月复查增强CT,显示碘油沉积良好,增强器扫描未见局部强化灶(图2d)。



a:病例1治疗前;b:病例1经DEB-TACE治疗后3个月;c:病例2治疗前;d:病例2经cTACE治疗后3个月

图2 典型病例治疗前后腹部CT

3 讨论

原发性肝癌首选的治疗方法是根治性手术,但对于丧失手术机会的患者,多采用肝动脉结扎、微波、射频以及冷冻等姑息性治疗方式。有文献报道称原发性肝癌的肝动脉在肝供血中占90%~99%[9]。自1976年首次报道采用TACE治疗肝肿瘤后,TACE在国内迅速成为姑息性治疗肝癌的首选方法,其作用机制主要是利用肝和肝肿瘤的供血特点,采用栓塞剂栓塞肝肿瘤病灶的供血动脉,致使肿瘤病灶坏死、缺血,以缩小肿瘤,同时局部灌注化疗药物,将癌细胞杀死,从而达到治疗的目的[10-11]。

TACE的治疗效果主要和栓塞剂能否完全栓塞肿瘤病灶供血血管有关[12]。目前临床常用的栓塞剂有碘油乳剂、聚乙烯醇以及明胶海绵等,其中碘油乳剂和明胶海绵最为常用。本研究cTACE组采用的是碘油乳剂作为液体栓塞材料,具有极高的选择性,能够进入80%的肿瘤组织,其能够将化疗药物传送至靶部位,并且还能够维持药物浓度,在X射线下,碘油清晰可见,其能够通过动静脉交汇处进入肝门静脉,从而形成双栓塞而加强疗效[13]。但也存在不足之处,随着时间的延长,碘油在肿瘤组织中会减少并消失,肿瘤血管会出现再通或产生新生血管,从而建立新生侧支循环,导致新的肿瘤病灶产生,进一步加重患者的病情。新型的化疗药物载体研制成为医学工作者不断探寻的课题,载药栓塞微球作为新型的化疗栓塞剂,其操作和cTACE相同,不同的是DEB-TACE是以载药微球为栓塞剂,其表面存在许多微孔,在栓塞血管的同时还能够通过少量血流,不仅能够抑制肿瘤生长,还能在一定程度上避免因为缺氧刺激导致新肿瘤供血血管产生,且负载在载药栓塞微球上的化疗药物能够缓慢释放,长时间作用于肿瘤病灶,从而延长对肿瘤作用的时间[14-15]。本研究采用的是负载吡柔比星的CalliSpheres®载药栓塞微球,结果显示,DEB-TACE组治疗后总有效率明显高于cTACE组,且DEB-TACE组术后2年生存率明显高于cTACE组,提示DEB-TACE治疗大肝癌能够明显提高生存率。国外学者的研究显示,载药微球组和传统TACE在局部和整体肿瘤缓解率、中位肿瘤进展时间和术后1年、2年生存率方面比较差异无统计学意义[16],可能是其纳入患者均为多病灶肝癌患者。Facciorusso等[17]的一项单中心研究显示,DEB-TACE的客观缓解率明显优于cTACE,中位生存时间也明显长于cTACE。徐文杰等[18]采用DEB-TACE术后1个月肿瘤坏死率为64%~91%,平均(82.97±18.29)%,也明显高于cTACE,本研究结果与其类似,再一次证实DEB-TACE联合微波消融治疗大肝癌更具优

势。分析其原因为负载于载药栓塞微球上的化疗药物经肝动脉灌注后有缓解效果,能够长时间作用于肿瘤病灶,明显增加肿瘤组织缺氧坏死的强度和时间,提高肿瘤局部和整体缓解率,进而提高患者生存率[19-20]。

肝癌介入治疗的毒副作用难以避免[21]。本研究着重观察了肝癌TACE治疗后的肝毒性以及常见不良反应,提示DEB-TACE对大肝癌患者肝功能损害更小,术后相同时间内肝功能恢复更明显,经TACE后患者均出现发热、呕吐、腹痛和腹胀等常见的不良反应,其中DEB-TACE组腹痛和腹胀发生率明显低于cTACE组。2组结果的差异可能与栓塞材料有关,载药栓塞微球能够减少化疗药物外渗,有效降低药物峰值浓度,从而减轻药物的不良反应。目前已有大量文献报道证实了DEB-TACE能够降低术后并发症和不良反应的发生率[22-24]。

综上所述,DEB-TACE作为新型的载药栓塞治疗方法,其联合微波消融术治疗大肝癌的疗效和安全性均明显优于cTACE,且能够提高患者的近期生存率。

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·临床研究·

半肩关节置换术治疗肱骨近端复杂骨折的效果分析

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[摘 要] **目的** 比较半肩关节置换术与切开复位内固定术治疗肱骨近端复杂骨折的临床效果,为临床术式选择提供参考。**方法** 回顾性分析2012年2月至2018年10月在陆军军医大学第一附属医院诊断为肱骨近端复杂骨折的50例患者的临床资料,按术式的不同分为切开复位内固定组28例(内固定组)与半肩关节置换组22例(置换组)。比较2组患者手术时间和肩关节前屈、外展、外旋及内旋角度,采用ASES、UCLA、SST、VAS评价2种术式的肩关节功能,分析手术并发症。**结果** 置换组患者手术时间和出血量均少于内固定组,差异有统计学意义($P<0.05$);术后1年,置换组与内固定组的前屈、外展、外旋及内旋角度分别为(108.37±12.16)°、(96.58±9.09)°、(33.42±3.89)°、(57.21±6.69)°与(95.24±10.32)°、(85.54±8.47)°、(28.35±3.77)°、(48.79±3.53)°,置换组患者各功能活动角度明显高于内固定组;ASES、UCLA、SST、VAS优于内固定组;置换组患者的并发症发生率也低于内固定组,差异均有统计学意义($P<0.05$)。**结论** 与切开复位内固定术比较,半肩关节置换术治疗肱骨近端复杂骨折的手术时间更短、手术创伤更小,术后肩关节功能活动度恢复满意,并发症发生率低,具有更好的临床治疗效果。

[关键词] 肱骨;近端骨折;内固定;肩关节;置换术;切开复位;假体置入;骨质疏松

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Curative effect analysis of hemi arthroplasty of the shoulder for the treatment of complex proximal humeral fractures

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Abstract: Objective To compare the clinical effects of hemi arthroplasty of the shoulder and open reduction and internal fixation in the treatment of complex proximal humeral fractures,and to provide a reference for the selection of clinical surgical methods. **Methods** The clinical data of 50 patients diagnosed as complex proximal humerus fractures in the first affiliated hospital of the Army Medical University from February 2012 to October 2018 were retrospectively analyzed. According to different surgical methods,the patients were divided into the open reduction and internal fixation group (internal fixation group,28 cases) and the hemihumeral joint replacement group (replacement group,22 cases). The operation time,forward flexion, abduction, outward rotation and inward rotation angles of the shoulder joint in the two groups were compared,and the shoulder joint functions of the two surgical methods were evaluated by ASES,UCLA,SST and VAS scores,and the surgical complications were analyzed. **Results** The operation time and blood loss in the replacement group were less than those in the internal fixation group with statistically significant difference ($P<0.05$). One year after surgery,the angles of anterior flexion,abduction,external rotation and internal rotation in the replacement group and the internal fixation group were (108.37±12.16)°,(96.58±9.09)°,(33.42±3.89)°,

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