APPROACH TOWARDS DEVELOPING AN ALGORITHM FOR GAP NONUNION

Orthopaedics

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ABSTRACT

Back ground and objectives The treatment of Gap or Defect non-union presents a formidable challenge to Orthopaedic surgeons. Not only a union but also good functional outcome is the target of modern-day Orthopaedics. The objective of this study is to consider knowledge of all treatment modalities, time frame, and functional results of long bone defects and develop an algorithm.

Summary The study is designed as retrospective, prospective observational study. It is conducted in tertiary care hospital (MIOT Hospitals, Chennai). Initial evaluation of all cases were done by Maurizio Catagni's Classification. Type of surgeries, time spent in hospital, union time were calculated. Patients were followed up for a period of 1 year. Patients with average defect size of 6.29cm on an average underwent 4.47 procedures and for an overall time of 17.8 weeks with around 83.80 % of individuals were able to return to their preinjury activity level. Analysis of all data was done and algorithm developed.

KEYWORDS

Gap or Defect nonunion , Catagni. CSBD , RABG, ASAMI ,Karlström-Olerud's, Cattneo

INTRODUCTION

Gap nonunion is characterized by loss of segment of long bone and occurs in

- Open fractures with bone loss,
- Resection of tumours,
- excision of sequestered segments,
- Pseudoarthrosis excision, etc.

The ends of the fragments may be viable but bone union across the defect is impossible. As time passes the fragments become atrophic. Gap non-union occur causing Infected or noninfected critical-sized bone defects (CSBD)^[1].

Managing gap non-union involves highest level of knowledge, experience, skill and hard work. It also needs patience on the part of surgeon and the patient. Repeated counselling, reassurances is of utmost importance. Regular follow-ups for assessment and reassessment are required. Individual cases demand discreet and continuous assessment time and again. It needs planning and precise

implementation of the plan. It also requires flexibility to adapt changes and anticipation of the next step necessary.

In this study, an endeavour would be made to study most time-tested methods adapted all over the world and to exclude experimental methods.

Rational for study

In addition to the considerable costs, multiple surgeries cause patients to have ongoing pain, swelling, stiffness and impaired function. Review of the literature confirms a paucity of comparable data on gap/defect non-union. This could also guide the design of more focused research in this area.

Aim of Study

This study aims analyse Gap non-union treated by different methods at tertiary level trauma centre and develop an algorithm for future management.

Review of Literature

Table 1. Evolution of management of bone defects

Year	Author	TITLE	PRINCIPLE USED
1905	Huntington[2]	Case of bone transference: Use segment of fibula.	Fibular transference
1943	Boyd et al[3]	The treatment of difficult and unusual nonunion	Cortical tibial graft
1945	Harmon PH[4]	surgical approach to posterior tibia for bone grafting	Posterior grafting
1947	Miller et al[5]	The repair of defects radius with fibula	Fibular bone grafts
1956	Nicoll et al[6]	Treatment of gaps in long bones	Cancellous inserts
1965	Urist et al[7]	Bone Formation by autoinduction	Autoinduction
1969	Ilizarov et al [8]	Replacement of defects of long tubular bones by means of one of their fragments	Distraction osteogenesis
1975	Taylor et al[9]	The free vascularized bone graft. A clinical extension of microvascular techniques.	free vascularized bone graft
1980	Grace et al [10]	The management of segmental bone loss associated with forearm fractures.	Cortical insert grafts
2000	Masquelet et al[11]	Reconstruction of the long bones by the induced membrane and spongy autograft	Masquelet Techniques
2001	Yokohama et al. [12]	Tibial defect management	Distraction osteogenesis & free vascularized graft
2006	Muscolo et al[13],	Massive allograft use in orthopedic oncology.	Massive allograft
2011	Fayaz et al[14]	stem cells in fracture healing and nonunion	Mesenchymal Stem Cells (MSCs)
2014	Lakhani et al [15]	Outcome of rail fixator in reconstructing bone gap	Rail fixator

Table 2. Benefits and Drawbacks of Management Methods of Bone Defects

Treatment	Major Benefits	Major Drawbacks
Amputation (Excluded)	Shortest treatment time	Total loss of limb function
Limb shortening	Short time; few complications	Some loss of limb function
Autologous cancellous bone graft	Generally applicable; reasonable results	Slow, unreliable, donor site morbidity.
Distraction osteogenesis	Best quality bone; Used in large defects	Frequent complications; long time to heal
Free vascularized graft	microvascular capability.	Donor site morbidity; fracture lack of hypertrophy
Local fibula	Acute spanning of defect; no special equipment required	Not always possible; not very strong; poor muscle function
Masquelet Technique	Biological technique	Under evaluation

Radiographic apparent bone gap (RABG)^[16] and infection were the only 2 covariates predicting nonunion outcome ($P = 0.046$ for infection). The RABG was determined by measuring the bone gap on each cortex and averaging over 4 cortices. Fractures achieving union had a RABG of 12 ± 1 mm versus 20 ± 2 mm in those going on to nonunion ($P < 0.01$). This remained significant when patients with infection were removed.

MAURIZIO CATAGNI'S CLASSIFICATION^[17]

- A1- Non infected mobile non-union
- A2- Non infected stiff hypertrophic non-union without deformity
- A3- Non infected Hypertrophic non-union with deformity
- B1- Non infected non-union with bone defect of up to 5 cm.
- B2- Non infected non-union with bone defect exceeding 5 cm.
- B3- Non infected non-union exceeding 10 cm with local scarring
- C1- Infected non-union with atrophy
- C2- Infected non-union with hypertrophy without deformity
- C3- Infected non-union with hypertrophy and deformity
- C4- Infected non-union with bone gap of less than 5 cm.
- C5- Infected non-union with bone gap between 5 and 10 cm.
- C6- Infected non-union with bone gap exceeding 10 cm.

Defect or Gap non-union concerns type B, C3, C4 and C5 and are subject of the study.

MATERIALS AND METHODOLOGY

MATERIALS

Study design

Retrospective-Prospective Observational Study

- Retrospective – cases in different phases of ongoing management i.e. with established gap nonunion or undergoing treatment or in follow-up
- Prospective – enrolled at the onset e.g. following RTA, etc.
- Observational- No interventional measures are taken for the sake of the study.

Sample size- 105

Calculation of sample size

Calculation of the sample size was done with nMASTER software with study done by Miller et al 2010

Hypothesis Testing for Single Proportion

Population Proportion $P_0 = .60$

Sample Proportion $P_a = .46$

Power (%) = 80

Alpha Error (%) = 5

Sided = 2

Sample size (n) = 97

Alpha Error(%)	Power(%)	Sample Size(n)
1	70	119
	80	145
	90	185
5	70	76
	80	97
	90	130
10	70	58
	80	76
	90	106

Setting-tertiary care teaching hospital (MIOT hospitals, Chennai)

Duration of Study-APRIL, 2014 to OCTOBER, 2015.

Recruitment of cases

Cases were recruited from OPD and IPD.

Total number recruited in their follow-up period- 86 patients.

Total number recruited on their treatment period- 19 patients.

Inclusion Criteria

All patients

- in the age range 15 to 60 years
- with segmental gap of bone of more than 1 cm and
- who were in different phases of treatment for gap non-union

Exclusion Criteria

Patients with

- irregular follow-ups and poor compliance
- distal neuro-vascular deficit
- substance abuse (nicotine, alcohol, illicit drugs etc.)

Follow-up

The follow-up interval was Monthly and as required and follow-up period was 1 year.

Methodology

Pre-operative protocol

- All recruited cases were classified by Maurizio Catagni's Classification.
- Each surgery recorded and complications documented.

Investigations

- Actual Size X-rays,
- CT scan where necessary.
- Relevant blood reports done.

Statistics

Data collection techniques

Data was collected from the OPD and IPD and notes in the Medical Registration Department (MRD).

Data analysis plan

Data was tabulated and statistically analysed in MS Excel and SPSS 17 (Chicago, Illinois).

Paired sample "t" test was done to compare the group means and the p value was calculated.

Probability value less than 5% was considered as statistically significant.

Observations

Table 3. Descriptive Statistics

Descriptive Statistics					
	N	Minimum	Maximum	Mean	Std. Deviation
AGE	105	16	56	30.58	9.281
LENGTH OF GAP-CM	105	1.80	14.00	6.2905	2.31731
DEFORMITY- DEGREES	105	0	30	4.81	8.968
SHORTENING-CM	105	0	9.0	1.070	2.2316
TOTAL NUMBER OF PROCEDURES DONE	105	2	10	4.47	1.592
TOTAL STAY IN HOSPITAL DAYS	105	13	49	27.23	10.054
UNION TIME- MONTHS	89	3	7	4.15	1.173
Karlstrom-Olerud's functional SCORE AT ADMISSION	72	13	16	14.92	1.084
Karlstrom-Olerud's functional SCORE 6 MONTHS	72	24	36	31.69	4.161
Karlstrom-Olerud's functional SCORE 1 YEAR	72	24	36	32.37	3.747
Valid N (listwise)	63				

Mean age of 30.58. Maximum patients (27) were of the age group 21 to 25 years

Table 4. Age Distribution

16 – 20 yrs	10
21 – 25 yrs	27
26 – 30 yrs	21
31 – 35 yrs	18
36 – 40 yrs	15
41 – 45 yrs	5
46 – 50 yrs	4
51 – 55 yrs	4
56 – 60 yrs	1

There were 82.9 percent Male patients in our study

Table 5. Sex Distribution

SEX					
	Frequency	Percent	Valid Percent	Cumulative Percent	
Valid MALE	87	82.9	82.9	82.9	
FEMALE	18	17.1	17.1	100.0	
Total	105	100.0	100.0		

61 percent of the patient had left side defects and rest had right side defects.

Table 6. Sex distribution

SIDE					
	Frequency	Percent	Valid Percent	Cumulative Percent	
Valid RIGHT	41	39.0		39.0	
LEFT	64	61.0		100.0	
Total	105	100.0	100.0		

Table 7. Occupation of sample population

OCCUPATION				
	Frequency	Percent	Valid Percent	Cumulative Percent
Valid BUSINESSMAN	9	8.6	8.6	8.6
CHEF	2	1.9	1.9	10.5
CLERK	8	7.6	7.6	18.1
DOCTOR	1	1.0	1.0	19.0
DRIVER	5	4.8	4.8	23.8
FARMER	2	1.9	1.9	25.7
HOUSEWIFE	4	3.8	3.8	29.5
MANUAL WORKER	9	8.6	8.6	38.1
NURSE	1	1.0	1.0	39.0
POLICE	4	3.8	3.8	42.9
SALESMAN	5	4.8	4.8	47.6
SHOPKEEPER	9	8.6	8.6	56.2
SOFTWARE	4	3.8	3.8	60.0
SOLDIER	5	4.8	4.8	64.8
STUDENT	19	18.1	18.1	82.9
SUPERVISOR	7	6.7	6.7	89.5
TEACHER	6	5.7	5.7	95.2
WHITE COLLAR	5	4.8	4.8	100.0
Total	105	100.0	100.0	

There were patients from various occupations. Students were the largest group comprising 18.1 percent of the sample.

Table 8. Causation of Gap Non-Union

CAUSATION OF GAP NONUNION				
	Frequency	Percent	Valid Percent	Cumulative Percent
Valid RTA	50	47.6	47.6	47.6
CHRONIC OSTEOMYELITIS	12	11.4	11.4	59.0
IMPLANT FAILURE	17	16.2	16.2	75.2
TUMOUR	15	14.3	14.3	89.5
FIREARM	4	3.8	3.8	93.3
BOMBLAST	4	3.8	3.8	97.1
CONGENITAL	3	2.9	2.9	100.0
Total	105	100.0	100.0	

Most of the Gaps were caused by Road traffic accidents comprising 47.6 percent of the population.

Figure 1. Causation of Gap Non-Union**Table 9. Bone involved**

BONE INVOLVED				
	Frequency	Percent	Valid Percent	Cumulative Percent
Valid RADIUS	18	17.1	17.1	17.1
ULNA	6	5.7	5.7	22.9
HUMERUS	9	8.6	8.6	31.4
FEMUR	21	20.0	20.0	51.4
TIBIA	51	48.6	48.6	100.0
Total	105	100.0	100.0	

Maximum number of defects was seen in the Tibia comprising of 48.6 percent of the sample size.

Figure 2. Involvement of different bones.**Table 10. Part of bone involved**

PART OF BONE				
	Frequency	Percent	Valid Percent	Cumulative Percent
Valid DIAPHYSEAL	90	85.7	85.7	85.7
METAPHYSEAL	12	11.4	11.4	97.1
ARTICULAR	3	2.9	2.9	100.0
Total	105	100.0	100.0	

Table 11. Nature of deformity

NATURE OF DEFORMITY				
	Frequency	Percent	Valid Percent	Cumulative Percent
Valid MOBILE	9	8.6	8.6	8.6
STIFF	18	17.1	17.1	25.7
NO	78	74.3	74.3	100.0
Total	105	100.0	100.0	

There was no deformity in 74.3 percent of patients and stiff deformity

in 17.1% and mobile deformity in 8.6 percent of patients.

Table 12. Infection Status.

INFECTION STATUS				
	Frequency	Percent	Valid Percent	Cumulative Percent
Valid YES	22	21.0	21.0	21.0
NO	68	64.8	64.8	85.7
QUESCENT	15	14.3	14.3	100.0
Total	105	100.0	100.0	

Infection was present in 21 percent; another 14.3 percent had quiescent infection.

Table 13. Infection Status in Each Bone

	Yes	No	Quescent
tibia	9	36	5
femur	3	15	3
humerus	1	5	3
radius	7	10	1
ulna	2	1	3

Table 14. Catagnio types

CATAGNIO TYPE				
	Frequency	Percent	Valid Percent	Cumulative Percent
Valid B1	12	11.4	11.4	11.4
B2	41	39.0	39.0	50.5
B3	15	14.3	14.3	64.8
C4	6	5.7	5.7	70.5
C5	29	27.6	27.6	98.1
C6	2	1.9	1.9	100.0
Total	105	100.0	100.0

Figure 2. Catagnio Types

Catagnio type B2 e.i. non-infected gap-nonunion with gaps of 5 to 10 cm was the major group with 39 percent of cases.

Table 14. Soft tissue condition.

SOFT TISSUE CONDITION				
	Frequency	Percent	Valid Percent	Cumulative Percent
Valid NORMAL	69	65.7	65.7	65.7
SINUS	12	11.4	11.4	77.1
CICATRISED	16	15.2	15.2	92.4
FLAP COVER	4	3.8	3.8	96.2
DISCOLOURATION	4	3.8	3.8	100.0
Total	105	100.0	100.0	

GENERAL PRINCIPLES OF TREATMENT OF GAP NONUNION

Goals :

- Viable environment around the fracture site and
- Fracture stability.
- bridging the Gap

ESSENTIAL STEPS

(1) CONTROL OF INFECTION

The treatment of nonunion begins with removal of all metallic implants and sequestrum. Fracture ends freshened. Proper antibiotics given based on culture and sensitivity reports.

(2) STABILISATION OF BONES

Stabilization of the bone fragments allows the mechanical stimulus to influence the local vascularization.

Stabilization of bone can be done with**1. Internal Fixation**

- A) Nailing
- B) Plating
- C) Nailing with augmentation / antirotation plating
- D) Dual plating / Orthogonal plating

2. External Fixation

- A) AO universal fixator –uniplanar or multiplanar / LRS
- B) Ilizarov ring fixator
- D) Hybrid fixator

3. Combined Internal And External Fixation Device**(3) BONE GRAFTING**

Different types of grafts or transport of segment.

1. Autogenic bone graft
 - a. Cancellous grafts
 - b. Cortical inserts
 - c. Rib grafts
2. Free fibular graft,
3. Tibialisation of fibula
4. Tibio-Fibular synostosis.
5. Distraction osteogenesis

Posterior bone grafting and tibiofibular synostosis **Fibular Graft** **Fibula-pro-tibia transfer** **Distraction osteogenesis / Segment transport****Figure 3. Different types of fixation**

- (4) **MOBILISATION** - fourth step is to mobilize the joint to avoid contracture and arthrofibrosis.

- (5) **ACHIEVE UNION** – Fifth step is to achieve union of bone.

- (6) **IMPROVE BONE STRENGTH**- Sixth step is to strengthen the bone union and work for consolidation.

- (7) **REHABILITATION** final step.

Table 15. initial fixation.

INITIAL FIXATION					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	PLATING	29	27.6	27.6	27.6
	IM NAIL	23	21.9	21.9	49.5
	IM NAIL + AUGMENTATION PLATE	11	10.5	10.5	60.0
	ORTHOGONAL PLATING	9	8.6	8.6	68.6
	INTRAMEDULLARY WIRE	2	1.9	1.9	70.5
	RING FIXATOR	26	24.8	24.8	95.2
	AO FIXATOR	2	1.9	1.9	97.1
	PLATING+AO FIXATOR	2	1.9	1.9	99.0
	COMBINATION	1	1.0	1.0	100.0
	Total	105	100.0	100.0

Figure 4. Initial fixation

Initial fixation was done by plating in 27.6 percent and ring fixator was done in 24.8 percent of cases. These were the two major groups.

Table 16. Type of bone grafting.

TYPE OF BONE GRAFTING					
	Frequency	Percent	Valid Percent	Cumulative Percent	
Valid	RIB+CALCELLOUS GRAFT	19	18.1	18.1	18.1
	POSTERIOR GRAFTING	23	21.9	21.9	40.0
	SEGMENT TRANSPORT	18	17.1	17.1	57.1
	CANCELLOUS	5	4.8	4.8	61.9
	FIBULA	18	17.1	17.1	79.0
	CORTICAL STRUT GRAFT	11	10.5	10.5	89.5
	TURNPLASTY	3	2.9	2.9	92.4
	SEGMENT TRANSPORT+POSTERIOR GRAFTING	8	7.6	7.6	100.0
Total		105	100.0	100.0

Figure 5. Type of bone grafting

21.9 percent of patients underwent posterior grafting, all of which were Tibial Gap-nonunion.

RESULTS

32 cases had union within 3 months. 16 cases failed to unite until the end of the study. Rest united at different periods of time.

Overall average time of union was 4.15 months which translated into 4.15x30=124.5 days=17.78weeks roughly.

Table 17. Average time of union

	average time of bone union
radius	3.24
ulna	3.35
humerus	3.5
tibia	4.53
femur	4.28
overall	4.15

Figure 5. Average time of union

The patient is assessed by ASAMI^[18] bone criteria, ASAMI functional criteria, Cattno et al criteria and Karlström-Olerud's^[19] functional evaluation criteria for lower limbs at onset of treatment, at 6 months and 1 year of treatment.

Time spent in hospital, total numbers of surgeries, union time were calculated.

The ASAMI bone score was Excellent in 17.1 % of cases in 6 months and 20 percent of cases in 1 year. As ASAMI does not consider bone grafting as Excellent so many of the cases had to be categorized into Good. Percentage of Good was 62 at both 6 months and 1 year. Values were statistically significant with P value less than 0.05. One case was a

COMPARISON OF DIFFERENT STUDIES

Table 18. Comparison between different studies

Author	Year	No. of patients	Bone	Treatment	Time of treatment (in weeks)	Size of Defect (average in cm)	Rate of Union
Weiland et al. [20]	1983	32/10	Tibia/Humerus	FVFG	-----	15.8	87.5%
Paley et [21] al.	1989	25	Tibia	CD	-----	6.2	100%
Green[22]	1994	32	Skeletal defect	15 ABG/ 17 CD	ABG 31.6/ CD 38.4	ABG 4/CD 5	ABG 86.6% CD 94.1%
Yokohama et al.	2001	8	Tibia	4 CD/4 FVFG	CD37.3/FVFG 25.1	CD 4.6/FVFG 7.3	100%/75%
Kocaoglu et al. [23]	2006	13	Tibia/Femur	CD+IMN	19.3	10	84.6%
Morasiewicz et al. [24]	2007	16	Femur	CD	-----	-----	93.75%
OUR STUDY	2014-15	105	DIFFERENT BONES	DIFFERENT TECHNIQUES	4.15 X 30 =124.5 /7=17.8	6.29	89/105= 84.76%

failure as it has undergone amputation following recurrence of tumour. The ASAMI functional score was Excellent in 53.3 % of cases in 6 months and 54.3 percent of cases in 1 year. Percentage of Good was 27.6 and 29.5 at 6 months and 1 year respectively. The Cattno score was U1/I2/F2 (solid union with no infection and full function) was seen in 79 % of cases in 6 months and 81.9% of cases in 1 year.

Karlström-Olerud's functional evaluation criteria for lower limbs (femur and tibia gaps) score was 14.92 at admission, 31.69 at 6 months and 32.38 at 1 year. Cross tabulation values were statistically in all three criteria with significant with P value less than 0.05.

Overall return to profession percentage was 83.80%.

The average bone defect was 6.29cm, which is comparable to other reports.

The average time of union in our patients was 4.15 months (Range 3 to 7 months) which was also comparable to other studies.

The treatment goal could be achieved in 89 out of 105 patients (84.76 %).

Algorithm on management of Gap non-union

DISCUSSION

Our study demonstrates that there is no single panacea for Gap Nonunion management. Combining different methods can fetch favorable results. This study is unique with respect to role of different combined methods as opposed to one single method or one single intervention.

CONCLUSION

The decision to intervene in Gap-non-union is a compulsion rather than a choice. Many methods combine and many steps are taken to reach this goal. Our study concludes that though the methods may be different, time consumed may vary, but significantly favorable results can be obtained with planning. Bone is precious, and reconstructing Gap nonunion remains a challenge till date.

Case 1- 25 year old man presented with discharging sinus with X-ray showing sequestrum

Sequestrum along with a length of infected bone was excised.

Bone was temporarily fixed with plates. In the second sitting after control of infection, ribs were harvested.

Union is achieved in 4 months

Case 2 – 35 year old lady presented with open injury around the distal thigh with comminuted fracture of femur with bone loss

The bone was initially fixed by AO ex-fix. Wound was treated with Vacuum Dressing. Later Exfix was removed and internal fixation was done with locking plate and flap cover was done together.

Orthogonal plating with rib grafting was done in the next sitting

5 month X- ray showed union and 1 year follow-up showed consolidation of graft with full functional recovery

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