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STUDY OF SKIN STAPLES AND CONVENTIONAL SUTURES FOR ABDOMINAL CLEAN WOUND SKIN CLOSURE: A RANDOMIZED CONTROL TRIAL

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HOW TO CITE THIS ARTICLE:

Deepak R Chavan, B. B. Metan, Sachin Kadlewad, Bharath S. "Study of Skin Staples and Conventional Sutures for Abdominal Clean Wound Skin Closure: A Randomized Control Trial". Journal of Evolution of Medical and Dental Sciences 2014; Vol. 3, Issue 20, May 19; Page: 5626-5636, DOI: 10.14260/jemds/2014/2639

ABSTRACT: OBJECTIVES: The objectives of this study were to study the total cost and operative time required for suture and staple repairs, to study the effect on wound healing and infection rate with the use of sutures and staples, to study the cosmetic results of these two techniques and to study the degree of patient's acceptance with the two techniques. **MATERIALS AND METHODS: Source of Data:** The study was conducted on 100 patients who undergoing elective surgery from January 2010 to March 2014 in BLDE UNIVERSITY, Shri B M Patil medical college Bijapur. The patients were randomly selected to receive either suture or staple repair. **METHOD OF COLLECTION OF DATA:** DURING OPERATION- from operating surgeon. **Post operatively:** from patient's input. **Supply of Suture and Staples:** from pharmacy. **FOLLOW UP OF PATIENTS:** Patients came for follow up to out-patient Department After discharge. **INCLUSION CRITERIA:** Patients undergoing elective abdominal surgery, with clean wound. **EXCLUSION CRITERIA:** Patients having lacerated wounds with skin loss. **RESULT:** The study groups included 100 patients who underwent wound closure by staplers and 100 patients who underwent the silk suturing. The youngest patient was aged 2 year and the oldest was 75 years old. The commonest region of the surgical wounds in this study was inguinal, 20 in staplers and 20 in suture group. The time taken for wound closure using staplers showed statistically significant difference over silk suture closure. It took the stapler four times less duration to perform wound closure. The appearance of the scar among the staple groups was good in 90% of those who returned for follow up at one month, 10% had average scar. The average cost of using staple was higher than silk suture. Patient acceptance was better in the staple group with less pain during removal as compared to suture group. There were four complications in the staple group in the form of wound infection and ten cases of postoperative wound infection in the suture group. Average VAS of patients in staple group at the end of one month was 71.88 (± 5.50) while the average for suture group was 64.44 (± 6.17). P value calculated using Student's Unpaired "T" test. P value was <0.0001 which was highly significant.

KEYWORDS: Skin Staples, Wound Healing, Wound Infection, Stainless Steel staples.

INTRODUCTION: Surgery is derived from the earlier name chirurgery, which means handwork. It is a science and art that shows the manner how to work man's body exercising all manual operations necessary to heal or as much as possible by using of most expedient medicines.

Brilliant developments of surgical skills and instrumentation have provided a precise understanding of an operative intervention. Today most surgical procedures are assessed by rigorous scientific methods, and such procedures become reproducible and predictable. Elaborate algorithms are available to calculate the requirement to replace or repair, to lengthen or shorten, to ablate or enhance, and to drain or not. However traditional axioms are often contravened. Urgent operations and insertion of foreign bodies are undertaken when one is confronted with acute sepsis; adhesive

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and staples are substituted for sutures; balloons challenge the bypass, and lasers, the scalpel. The essence of modern surgeon is now, more than ever before, that quality called JUDGEMENT-the ability to know what to use, when to use it, and for how long.

Any surgical intervention will result in a wound in order to get access to and deal with underlying pathology. In this situation surgeon's task to minimize the adverse effects of wounds, remove or repair the damaged structures and harness the process of wound healing to restore function.

The principle aims of tissue repair of surgical skin incisions are rapid acquisition of strength and minimum tissue damage with minimum inflammation and a good scar. Many factors including the choice of suture materials and its placements influence these aims. But of particular relevance is the accurate co-optation of dermal edges; eversion or inversion leads to sub optimal healing.

For many years it has been possible to approximate the skin edges using sutures. However, sutures have the disadvantages of consuming more time in applying with a cosmetically inferior scar. The use of automatic stapling device for skin closure has become more popular of late to overcome these disadvantages. At the present time cost effectiveness of these is debatable.

Hence this study was undertaken WITH THESE OBJECTIVES:

1. To study the total cost and operative time required for suture and staple Repairs.
2. To study the effect on wound healing and infection rate with the use of Sutures and staples.
3. To study the cosmetic results of these two techniques.
4. To study the degree of patients acceptance with the two techniques.

MATERIALS AND METHODS:

Source of Data: The study was conducted on 100 patients who undergoing elective surgery from January 2010 to June 2014; randomly selecting patients, to receive either suture or staple repair. 100 patients underwent abdominal skin closure with either staples or conventional vertical mattress suturing with Ethylon. Out of the 100 patients, 50 underwent skin closure with Stainless steel skin staples and the remaining 50 with vertical mattress suturing with Ethylon All these patients were allotted to either group according to random number table.

Sample size: 100.

The following formula was used to calculate the sample size required for this study.

$$N = [2(Z\alpha + Z\beta)^2 pq] / d^2$$

$$P = (p_1 + p_2) / 2 = (12 + 0) / 2 = 6$$

$$q = 100 - p$$

$$d = 12 - 0 = 12$$

$$Z\alpha = 1.65$$

$$Z\beta = 0.84$$

$$N = 48$$

So calculated sample size on each wing is 48, taking into account cases losing to follow up, sample size on each wing would be 50

$$(50 + 50 = 100)$$

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Method of Collection of Data: Inclusion criteria: Patients undergoing elective abdominal surgery, with clean wound.

Exclusion Criteria: Patients having lacerated wounds with skin loss.

Data was collected:

DURING OPERATION: from operating surgeon.

POST OPERATIVELY: from patients input.

SUPPLY OF SUTURE AND STAPLES: From pharmacy.

FOLLOW UP PATIENTS: Patients coming for follow up to out-patient Department After hospitalisation.

The wounds were evaluated at 1 months follow up which were rated for cosmesis on a previously validated cosmesis Visual Analogue Score which has been demonstrated to be reliable and valid outcome measure of cosmesis. The cosmetic VAS is a 100 -mm line with worst scar at 0 and best scar at 100.

A senior surgeon rated photographs unaware of the method used to close the wound using the line as a continuous entity. The surgeon marked the patient's scar on the line. The score was then measured in millimetres from 0 to 100. The mean VAS for each group was calculated.

Statistical evaluation was done after consulting the college statistician. Using the student's unpaired "T" test, the p value was calculated

RESULTS: The study groups included 50 patients who underwent wound closure by staplers and 50 patients who underwent the silk suturing. Among the stapler group, the youngest patient was aged 2 year and the oldest was 62 years old, with a median age of 30 years. The suture group has a three-year old patient as the youngest and 75 year old patient as the oldest. There were 38 males and 12 females in the stapler group while there were 42 male and 08 females in the suture group.

The commonest region of the surgical wounds in this study was inguinal, 20 in staplers and 20 in suture group, the regional distribution of surgical wounds in the suture group was mid line 10, mcBurney's 06, subcostal 04, transverse 04, paramedian 04 and other in 02 among the stapler group, there were 04 patients whose wound length belonged to group a (<5 cm), 30 in group b (5-10 cm) and 14 patient in group c (>10 cm). among the suture group, there were 2, 32 and 16 patients in groups a, b and c. there were no statistically significant differences between the two groups, with respect to patients' age, sex and wound length.

The time taken for wound closure using staplers showed statistically significant difference over silk suture closure. It took the stapler four times less duration to perform wound closure. with staplers the average time taken was 11 seconds whereas with silk suture, the time taken was 45 seconds per centimeter of wound length.

The difference between the two techniques was most striking in the group c wounds, which were longer than 10 cm. among group a wounds also there was a statistically significant difference between the stapler and suture groups. The average time taken for application of stapler in group a wound was 60 seconds whereas for the suture group, it was 240 seconds.

Subjective quantification of the pain during suture removal showed that 32 patients registered a score of 1, 14 had a score of 2, and 04 had a score of 3, among the stapler group of patients. There were no patients who registered a score of 5. Among the suture group they were 10

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patients who had a score of 1, 26 had score of 2, 10 had 3 and 04 had score of 4. in the suture group too there were no patients who registered a score of 5.

The cost of the procedure with stapler depended on the length of the wound. For group a wound, the average cost was rs.60.90, for group b it was rs. 90.80 and for group c it was rs. 172.50. The cost of silk suture was rs.35.35 (3 metric length) for majority of the cases. In 04 cases, which required more than 3 metric length of silk due to bigger wounds, the cost was higher (rs. 71.00).

In the postoperative period there were 02 cases of wound infection in the stapler group and 08 in the suture group. The overall rate of return for follow up at one month was 40% with similar rates for both the groups of patients. those who did come for follow up did not have any long-term complications.

The appearance of the scar among the staple groups was good in 90% of those who returned for follow up at one month, 10% had average scar, with widening or hypertrophy of the scar with itching. The cosmetic appearance of the scar was good in 60% of the cases in the suture group, with 30% with average and 10% poor scars.

Patients were followed up after discharge at 8th to 10th post-operative day for removal of staples. Cosmetic evaluation was done at 1 month follow up. No patients were lost to follow up. Average VAS of patients in staple group at the end of one month was 71.88 (± 5.50) while the average for suture group was 64.44(± 6.17). P value calculated using Student's Unpaired 'T' test. P value was <0.0001 which was highly significant.

DISCUSSION: The act of sewing is as old as Homo sapiens. In Susruta samhitha 600 BC there is mention of suture material made from animal sinews, braided horsehair, leather strips, and vegetable fibers. Surgical stapling was developed in 1908 by Hulti Humer in Australia. the original instrument was massive by today's standards weighing 7.5 pounds. Modifications performed by Von Petz provided a lighter and simpler device, and in 1934 Fredrick of Ulm designed an instrument that resembled the modern linear stapler. The next major advances came from Russia after World War II. In 1958, Ravich, who, through research and development, refined the instruments to their current state and wide spread use today^{1,2,3}

There are less studies available in the literature comparing the results of application staplers to various anatomic regions. Though Ranaboldo and Rowe-Jones have compared the results of stapler with subcuticular absorbable sutures for laparotomy wounds and divided them into lower and upper abdominal regions, no mention was made by them regarding the appearance of the scar at various sites.⁴ There was no significant benefit of staplers over subcuticular sutures in their study.

In the present study, the time taken to complete wound closure was significantly less with the use of staplers as compared to sutures. The average time required to approximate one centimeter of wound was 11 seconds with the stapler whereas with silk suture, it was 45 seconds, more than four times longer.

In the study by Ranaboldo et al, the rate of wound closure was 8 seconds/cm with stapler and 12.7 seconds/cm with sutures⁴. In our study, for a four-centimeter wound, the time taken with stapler was about 45 seconds whereas a similar wound required 3 minute with suture. Thus, there was a saving of 135 seconds or two and a quarter minutes.

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This is comparable with several other studies. Kanagaye observed that staplers were six times faster than standard sutures.⁵ Eldrup et al analyzed 137 patients and concluded that mechanical sutures took one third of the time taken by conventional sutures.⁶

Meiring et al have recorded that there was 80% time saving, whereas Harvey and Logan have reported 66.6% time saving with the use of staplers^{7,8} Medina dos Santos et al found in a prospective trial that the mean skin closure time with staple was 5 minutes and 25 minutes with nylon suture.⁹

For analysis of the cost factor, the wounds were divided into three groups depending on the length (less than 5 cm, 5cm to 10cm and more than 10 cm) and were named groups A, B and C respectively. The average cost of using skin stapler for group A wound was Rs. 61, for group B it was Rs. 91 and for group C it was Rs. 172. The cost of stapler use in general was significantly higher as compared to silk sutures, which had a cost of only Rs.35 per wound on average. This difference in cost has been well document by earlier studies as well.

Ranaboldo has concluded after studying 48 patients that, the cost of stapler use is five times higher than sutures.⁴ However, in the present study, on comparing the cost of using stapler in group A wounds alone showed no major difference. The benefit of time saved in this group alone (60 seconds with staplers versus 240 seconds with sutures) was significant enough to outweigh the minor cost difference. The cosmetic appearance of the wound was also better with use of staplers.

Medina dos Santos in their study found that the cost difference between conventional sutures and staplers was only slight.⁹ Orlinsky et al studied the cost related to both equipment and personnel time in a general emergency setting and found staplers to be more time and cost efficient in repairs performed by physicians' assistance.¹⁰

In a study by Kanagaye et al, the authors studied, additional factors that influence the cost such as, consumable in the operation theater and the physician time expended etc, and concluded that the overall cost of stapling is less than that of suturing.⁶ However, in the present study, analysis of these additional costs were not included. If these were to be also included, the cost of performing stapling should have come down further.

In the present study, three complications were encountered in the staple group in the form of wound infection. No other complications were seen. In the suture group, there were 08 cases with postoperative wound infection and 02 of which had partial wound dehiscence. These results are significantly less when compared with other studied. Kanagaye et al, in their study of 45 pediatric cases observed no complications in the staple group.

To summarize, considerable alteration has taken place from the conventional skin suture technique and switch over to the new era of cosmoes, in the forum of skin stapling to achieve a near virgin scar less skin.

CONCLUSION:

- The present study has demonstrated better cosmetic results and a slightly higher cost with the staples, but saving in closure time that was statistically significant and in agreement with the literature reviewed.
- The marvel of skin stapling has helped in eliminating the post operative pain and the infection, ensuring a near normal skin appearance.
- It is strongly believed that when available, use of staples for skin closure allows saving in time, an important factor mainly for closure of large and multiple incision.

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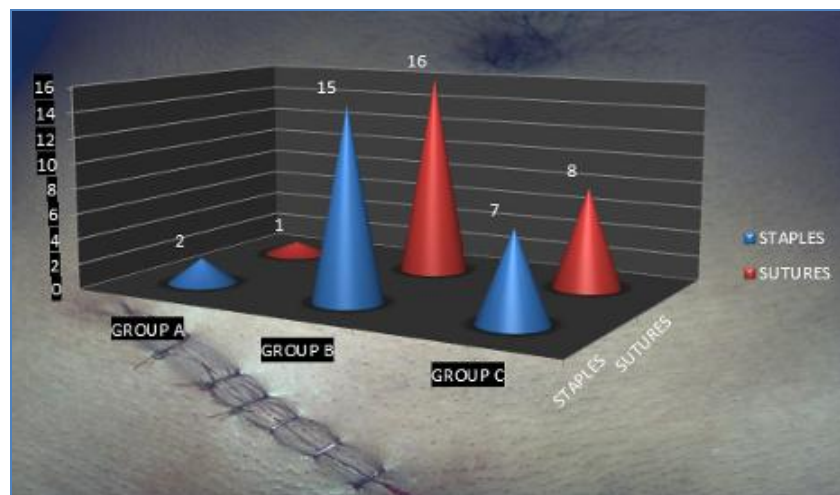
- Hence skin suture technology has kept pace with modern surgical technique, so it is imperative that a surgeon keeps skin staplers as a part of their armamentarium.

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Classification of Wounds:

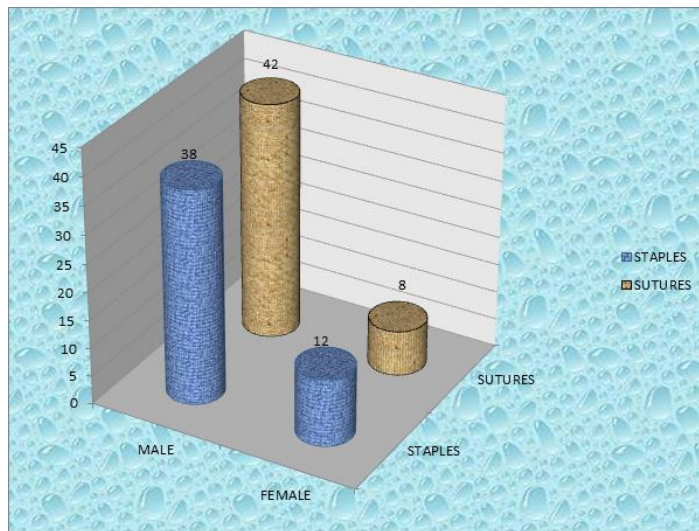
Group	A (1 TO 5 CMS)	B (5 TO 10 CMS)	C (>10 CMS)
Staplers	02	15	07
Sutures	01	16	08



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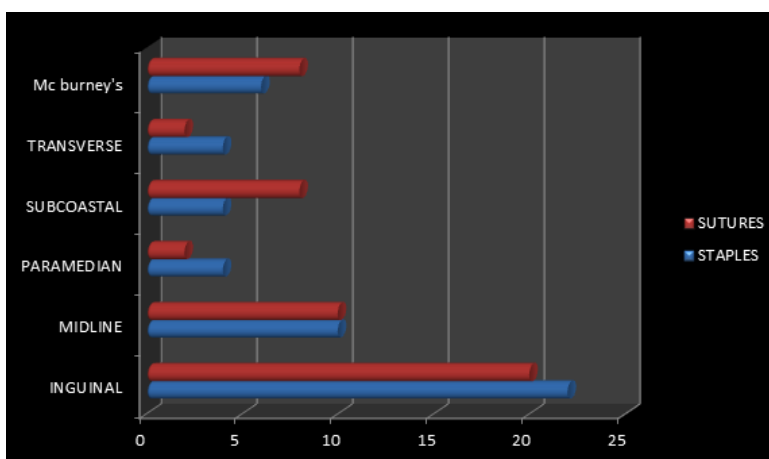
Sex distribution:

Staplers	38 males	12 females
Sutures	42 males	08 females



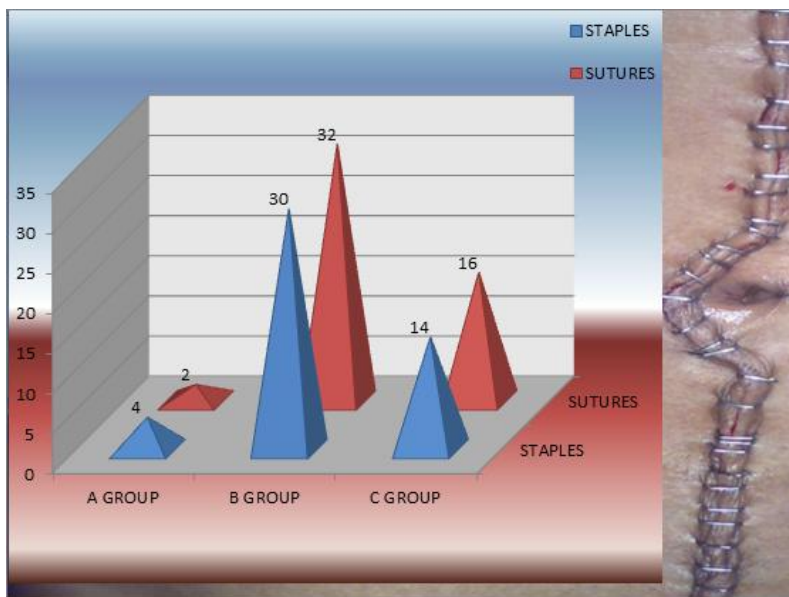
Region:

	INGUINAL	MIDLINE	PARA MEDIAN	SUB COASTAL	TRANSVERSE	MC BURNEY'S
STAPLERS	22	10	04	04	04	06
SUTURES	20	10	02	08	02	08

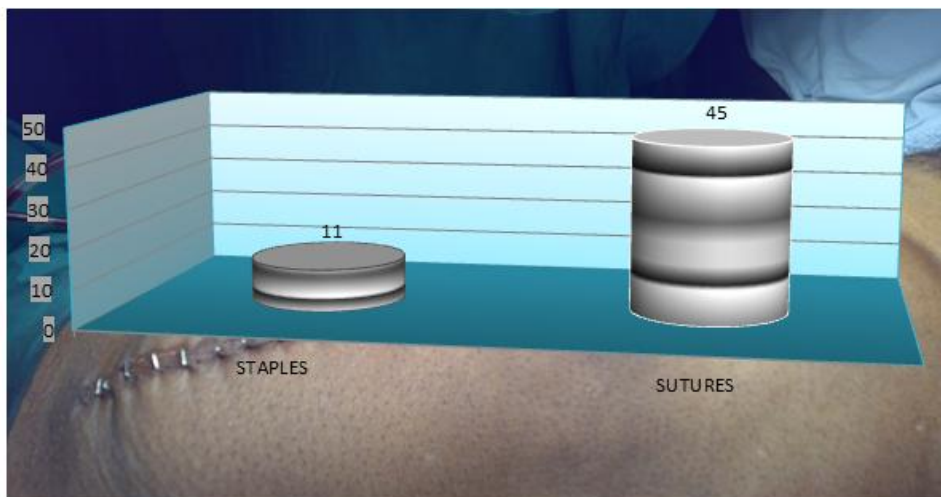


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Wound Distribution		
Wound Group	Staples	Sutures
A Group	04	02
B Group	30	32
C Group	14	16



TIME FACTOR		
TIME	STAPLERS	SUTURES
Sec/ cm	11	45



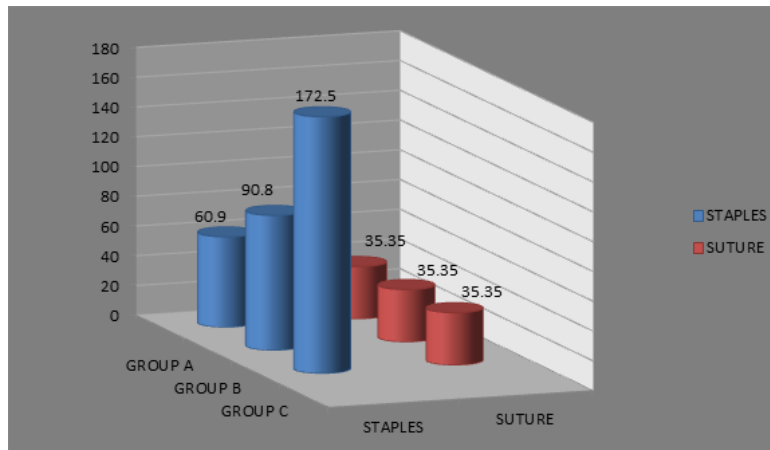
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Comparison:

	Staplers (Mean closure time)	Sutures (Mean closure time)
Medina dos Santos et al	5 Min	25 min
CT Ranabaldo et al	147 sec	224 sec
T Kanagaye et al	65 sec	397 sec
Our study	60 sec	240 sec

Groups vs Cost:

GROUPS	STAPLES	SUTURES
Group A (WL-up to 5cm)	Rs. 60.90	Rs. 35.35
Group B (WL - 5 to 10 cms)	Rs. 90.80	Rs. 35.35
Group C (WL > 10 cms)	Rs. 172.50	Rs. 35.35



Patients Acceptance:

	Staplers	Sutures
Scars (good)	90%	60%
Pain while removal (Self report - Scale 5)	04	20

Complications:

	Staplers	Sutures
Medina dos Santos et al	5/20 cases	3/20 cases
J.K. Kanagaye et al	2/45 cases	-
Our study	02/50 cases	08/50 cases

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Cosmetic Outcome:

	Staplers	Sutures	Value
VAS	71.88	64.44	<0.001 (H S)
SD7	5.50	6.17	



Stapler



INGUINAL INCISION



SUBCOSTAL INCISION STAPLES USED



Mc BURNEY'S INCISION



MID LINE incisions



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Date of Submission: 30/04/2014.

Date of Peer Review: 01/05/2014.

Date of Acceptance: 09/05/2014.

Date of Publishing: 19/05/2014.