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Original Research Article

Comparison of Seroprevalence of Transfusion Transmissible Infections Among Voluntary and Replacement Blood Donors in Silchar Medical College & Hospital Blood Centre - A Tertiary Care Centre

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Abstract:

Background: Transfusion-transmissible infections (TTIs) like HIV, hepatitis B virus (HBV), hepatitis C virus (HCV), syphilis and malaria can pose a significant threat to blood safety despite the obligatory screening. TTIs in blood donors vary considerably geographically in India and voluntary non-remunerated blood donors are usually thought safer, than replacement donors. This paper has compared TTIs seroprevalence rates between voluntary and replacement donors in the Silchar Medical College and Hospital (SMCH) Blood Centre, Assam, and explained demographic predictors of TTI positivity.

Methods: The study under question was a prospective cross-sectional study carried out between 1 February 2023 and 31 January 2024 at the SMCH Blood Centre, which is a tertiary care hospital in North-East India. All the potential donors between the ages 1865 years were enrolled through written informed consent. The demographic data and type of donor (voluntary or replacement) was used. HBsAg, anti-HCV and HIV-1/2 antibody and p24 antigen screening of sera were performed in third and fourth-generation ELISAs; syphilis and malaria were detected in rapid immunochromatographic assays; in line with the national regulations. Seroprevalence was calculated and the proportions analyzed by Pearson chi-square test ($p<0.05$).

Results: Out of 7, 536 donors, 5,394 (71.6) were replacement and 2,142 (28.4) were voluntary donors; 93.1% of them were men. In general, the TTI prevalence was 2.96 percent with 223 donors being seroreactive to at least one of the TTI. The most common diseases were HBV (0.97) and syphilis (1.02) and then there was HIV (0.50), HCV (0.40) and multiple infections (0.07); not a single donor was positive to malaria. Most infections were due to replacement donors (e.g. 92.2% of syphilis and 87.7% of HBV cases), however, the mixing of specific TTIs by type of donor was also statistically non-significant (2.931, $p=0.569$). Conversely, TTI positivity was highly age-dependent ($2=31.266$, $p=0.002$), with the highest percentage of seropositive donors being 2435 years old, and sex-dependent ($2=13.909$, $p=0.008$), where 96.4% of the seropositive donors were male.

Conclusion: TTIs still continue to be a significant issue among blood donors in this tertiary care centre and close to 3 percent of seemingly healthy blood donors have demonstrated some form of infection. TTI positivity was significantly dependent on age and male sex but not the donor type. It is necessary to improve the recruitment of voluntary non-remunerated donors, improving pre-donation counselling, and ensuring a high level of screening to increase the level of blood safety even further.

Keywords: Blood Donors; Transfusion-Transmissible Infections; Voluntary Donors; Replacement Donors; Hepatitis B; HIV; Syphilis; Assam.

Introduction

Blood transfusion forms a part of contemporary medical practice yet has a predisposed danger of infectious agent infection about a donor to a recipient. World Health Organization (WHO) estimates the total number of blood donor years to reach hundreds of millions a year all over the world

and insists that safe blood is an important part of universal health coverage [1]. The issue of transfusion-transmissible infections (TTIs), how HIV, HBV, HCV, syphilis and malaria are also a significant concern in low- and middle-income countries, given that the prevalence of backgrounds is higher than resources to pursue advanced screening methods could be available to date-off[1,3].

The risk-based guideline in the use of blood as being the safest is that of regular donors, non-paying and voluntary donors, who belong to low-risk groups as opposed to family donors, which are certainly not replacing a previous donor, as differentiated by WHO and global advisory bodies, whether in India or other countries, thus as a progressive shift towards voluntary donation and the elimination of universal screening of the five essential TTIs[2,8,9].

Reported TTI prevalence in the blood donor population is usually 1-3 percent in India with the dominance of HBV and HCV, although heterogeneity across states and time are common with differences in prevalence by the community, donor selection practices and as a test strategy [3,4,10,12,13].

Indian research has also compared TTIs in voluntary and replacement donors and tends to indicate a higher prevalence of TTI in replacement donors (2.0-2.8%) compared to voluntary donors (5,7,8,10). Giri et al. reported higher rates of TTI in replacement donors (2.0?2.8%):[5] and Garg et al. reported higher rates of HIV, HBV, HCV and syphilis in replacement donors (7). Later, Madhya Pradesh, Gujarat and Nadiad studies have also identified the types of donors and demographic disparities in TTI trends[6,9,11-13].

The North-East India, Assam being one of them is known to experience distinct epidemiology owing to the difference in ethnic groups, migration and endemicity of the infections like malaria and viral hepatitis.[4]. Nonetheless, available modern day data between TTIs of voluntary and replacement donors in the region studies are scarce especially involving tertiary care institutions which serve as referral centres.

The current research was conducted at the Blood Centre of the Silchar Medical College and Hospital (SMCH) which is a tertiary level facility and located in southern Assam.

The major aims were: (1) to estimate the seroprevalence of HIV, HBsAg, HCV syphilis and malaria among voluntary and replacement donors, (2) compare the distribution of the above diseases between the groups of donors and (3) describe the demographic profile of the donors, age and sex in terms of TTI positivity. To implement focused recruitment procedures and boosting screening policies and eventually increase the safety of transfusion in North-East India, it is necessary to create resistant local data.

Materials and Methods

Study Design and Setting: This was a prospective cross-sectional study conducted at the Blood Centre of Silchar Medical College & Hospital (SMCH), a tertiary care teaching hospital in Cachar district, Assam, India. The study period extended from 1 February 2023 to 31 January 2024. The Blood Centre serves both in-house clinical departments and peripheral facilities across the region.

Study Population, Inclusion and Exclusion Criteria: All individuals presenting for whole blood donation during the study period who met national eligibility criteria were considered for inclusion. Donors aged 18–65 years who fulfilled the “Criteria for Blood Donation” as per the Drugs and Cosmetics Act and associated guidelines, and who provided written informed consent for participation, were included. Both voluntary non-remunerated donors and family/replacement donors were enrolled. Donors were excluded if they were deferred (temporarily or permanently) based on standard medical and behavioural deferral criteria, or if they declined to provide consent for use of their anonymised data.

Sample Size and Sampling: A census sampling approach was used: all consecutive eligible donors during the 12-month period were included. In total, 7,536 donors were enrolled, comprising 5,394 replacement and 2,142 voluntary donors. Among them, 7,014 were male and 522 female. The sample size provided adequate power to detect clinically relevant differences in TTI seroprevalence between donor categories using chi-square tests, based on prior regional estimates.

Data Collection: After pre-donation counselling, eligible donors were informed about the study, and written consent was obtained. A structured questionnaire was used to record socio-demographic details (age, sex), type of donation (voluntary or replacement) and brief medical history. Donors then underwent standard physical examination and phlebotomy.

Unique identification numbers were used to link demographic information with laboratory results in an encrypted database. Any adverse reactions during or after donation were recorded in routine logs but were not the focus of this analysis.

Laboratory Testing: Approximately 3–5 mL of venous blood was drawn into plain tubes from each donor at the time of donation, and serum was separated by centrifugation. All samples were screened for the five mandatory TTIs in accordance with national guidelines.

- **HIV-1/2 and p24 antigen:** Tested using a fourth-generation Microlisa HIV Ag & Ab ELISA (J Mitra & Co., India), a sandwich enzyme immunoassay detecting both HIV-1/2 antibodies and p24 antigen.
- **HBsAg:** Detected using a third-generation MERILISA HBsAg ELISA (Meril Diagnostics, India), based on monoclonal anti-HBsAg antibodies in a microplate format.
- **Anti-HCV antibodies:** Assessed using a third-generation HCV Microlisa ELISA (J Mitra & Co., India), an indirect assay employing recombinant HCV antigens coated on microplate wells.
- **Syphilis:** Screened by a rapid immunochromatographic test (Syphicheck-WB / modified TPHA format) detecting antibodies to Treponema pallidum in whole blood or serum.
- **Malaria:** Screened using a rapid pan-malarial card test (Advantage Pan Malaria / Satya 2.0) detecting plasmodial lactate dehydrogenase (pLDH) antigens of Plasmodium species by a lateral-flow "sandwich" assay.

Tests were performed according to manufacturers' instructions. Optical density (OD) was measured at appropriate wavelengths using an automated ELISA reader. For ELISA-based assays, sample OD values were compared with kit-specific cut-off values derived from controls; values above cut-off were considered reactive. Indeterminate or borderline results were repeated; persistently equivocal donations were treated as reactive and units were discarded.

Quality Control: Internal quality control included routine use of kit-provided positive and negative controls on each plate or test strip batch. Reagents were stored and handled as per recommendations, and equipment was calibrated regularly. External quality assurance was maintained through participation in regional proficiency testing programmes.

Statistical Analysis: Data were entered into a password-protected spreadsheet and analysed with standard statistical software. Categorical variables were summarised as frequencies and percentages. Overall seroprevalence of each TTI (HBV, HCV, HIV, syphilis, malaria) and of any TTI was calculated as the proportion of reactive donations among all donations. Pearson's chi-square test was used to compare seropositivity between donor types (voluntary vs replacement), age categories (18–23, 24–35, 36–50, 51–65 years) and sex. A p-value <0.05 was considered statistically significant. Logistic regression models were planned to explore independent associations of donor characteristics with TTI positivity; detailed outputs are not presented here.

Ethical Considerations: The study protocol was reviewed and approved by the Institutional Ethics Committee of Silchar Medical College & Hospital.

All procedures conformed to the ethical principles of the Declaration of Helsinki and relevant national regulations. Donor identities were anonymised for analysis, and reactive donors were counselled and referred for appropriate follow-up care according to institutional policy.

Results

Donor Characteristics: A total of 7,536 blood donors were included. Replacement donors constituted 5,394 (71.58%), whereas 2,142 (28.42%) were voluntary donors. Overall, 7,014 donors (93.1%) were male and 522 (6.9%) female.

Table 1: Baseline characteristics of blood donors (n=7,536)

Characteristic	Category	n	%
Donor type	Replacement	5,394	71.6
	Voluntary	2,142	28.4
Sex	Male	7,014	93.1
	Female	522	6.9

In this setting, requiring ongoing reliance on family or patient-replacement donors, the results showed a strong skewing of the donor population to replacement donations (nearly three-quarters of all the units).

Male figures were very dominant as less than 7% of the donations were women, just the way it is recorded in most of the Indian blood centres. Such sex imbalance does not only have implications in expanding the donor pool; it also has implications in relation to the risk of sex-specific TTI.

Overall prevalence of TTIs: During the study period, 223 donors were seroreactive for at least one TTI, yielding an overall TTI prevalence of 2.96% (223/7,536). Syphilis (VDRL-reactive) and HBV were most common, followed by HIV and HCV; no malaria-reactive donor was identified.

Table 2: Overall seroprevalence of individual TTIs among donors (n=7,536)

Infection	Seroreactive donors (n)	Prevalence (%)
Syphilis (VDRL)	77	1.02
HBV (HBsAg)	73	0.97
HIV	38	0.50
HCV	30	0.40
Multiple infections	5	0.07
Malaria	0	0.00
Any TTI (overall)	223	**2.96**

Approximately, 3% of donors had at least one TTI, which assess the centre as being in the middle range of the Indian reports.

The first infections were HBV and syphilis whereas HIV and HCV exhibited lower but clinically significant prevalence. The lack of malaria-reactive units is also a suggestion of an efficient history screening of donors and comparatively low infection of the parasites in seemingly healthy donors, as well as in other Indian series malaria seropositivity has been extremely low or non-existent.

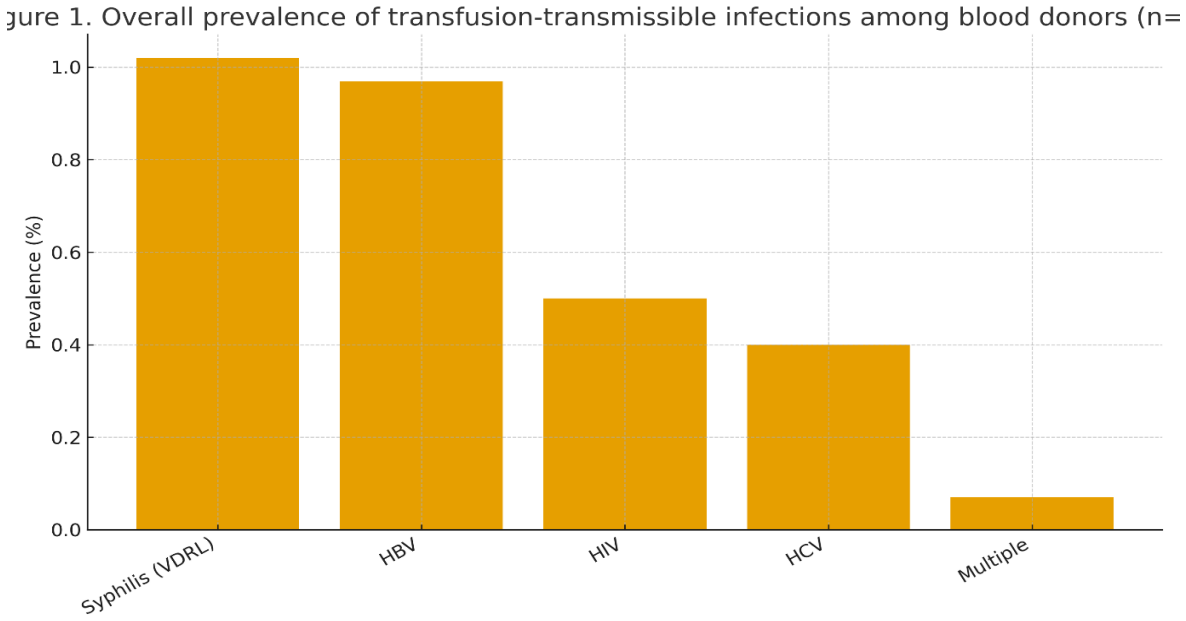

Figure 1: Distribution of Transfusion-Transmissible Infections among All Seroreactive Donors (N=223)

The graphic representation shows that both syphilis and HBV contributed to about two-thirds of all TTI-positive donation with a smaller yet not negligible share of HIV and HCV. There were uncommon but clinically significant multiple infections as they are morbidity-enhancing and indicate a common route of entry. This trend especially the prevalence of HBV and syphilis resembles results of various studies in India and across the region and highlights the necessity to maintain attention to sexually and parenterally transmitted diseases among the donors.

Comparison of TTIs between replacement and voluntary donors: When stratified by donor type, replacement donors contributed the vast majority of TTI-reactive cases across all infections.

Table 3: Distribution of TTI-positive donors by donor type

Infection	Replacement donor's n (%)	Voluntary donor's n (%)	Total n (%)
Syphilis (VDRL)	71 (92.21)	6 (7.79)	77 (100)
HBV (HBsAg)	64 (87.67)	9 (12.33)	73 (100)
HCV	29 (96.67)	1 (3.33)	30 (100)
HIV	35 (92.11)	3 (7.89)	38 (100)
Multiple infections	5 (100.00)	0 (0.00)	5 (100)
Any TTI	204 (91.5)	19 (8.5)	223 (100)

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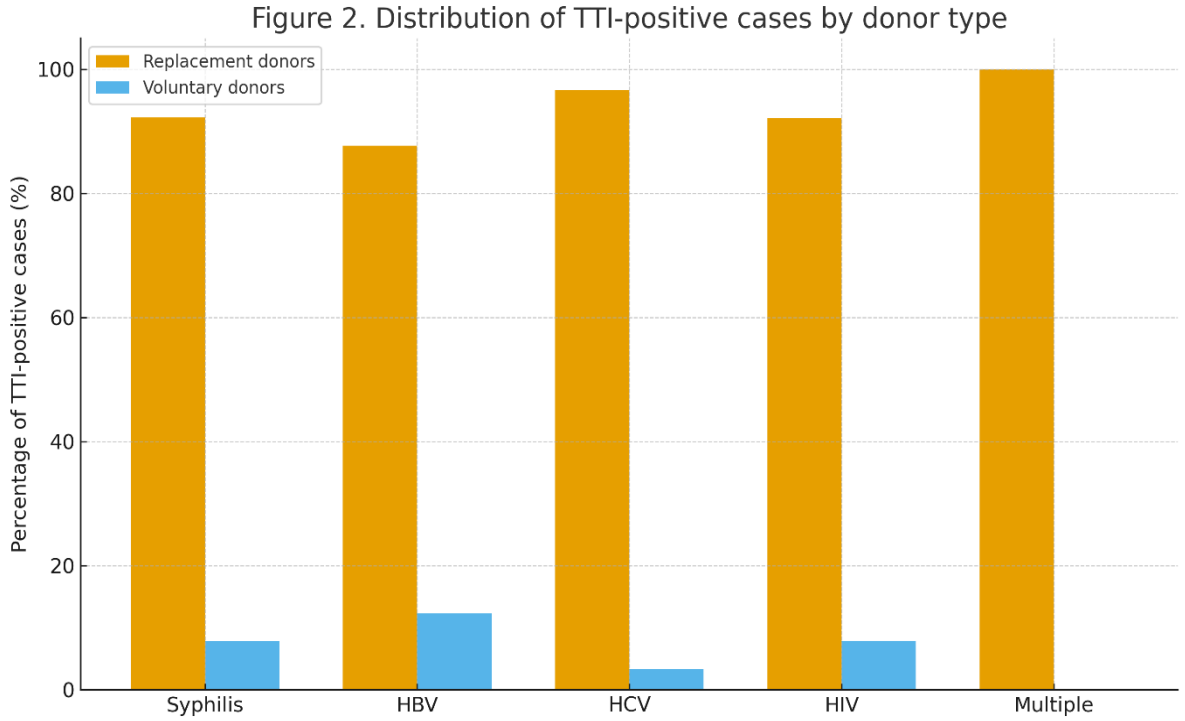

Figure 2: Proportion of TTI-Positive Donations among Replacement and Voluntary Donors

The figure graphically supports the fact that, in all the categories of infection, replacement donors provide a much greater proportion of TTI-positive units to the table than voluntary donors, although this difference is not statistically significant in the data. This tendency is of epidemiological significance: this is consistent with the world and national practice where voluntary non-payment donors are less likely to be involved in any type of risk and contributes to the current change in the direction of the necessity to reduce the aspect of the dependence on replacement donations.

Distribution of TTIs by age group: TTI seropositivity varied significantly by age.

Table 4: Distribution of TTI-positive donors by age group (n=223)

Age group (years)	Syphilis n (%)	HBV n (%)	HCV n (%)	HIV n (%)	Multiple n (%)	Total n (%)
18–23	5 (6.49)	11 (15.07)	7 (23.33)	4 (10.53)	1 (20.00)	28 (12.6)
24–35	30 (38.96)	45 (61.64)	15 (50.00)	23 (60.53)	4 (80.00)	117 (52.5)
36–50	30 (38.96)	15 (20.55)	7 (23.33)	11 (28.95)	0 (0.00)	63 (28.3)
51–65	12 (15.58)	2 (2.74)	1 (3.33)	0 (0.00)	0 (0.00)	15 (6.7)

Over fifty percent of all TTI-positive donors were 2435 years old, and this age bracket supported the majority burden of all types of infections below and over four fifths of multiple infections. The statistically significant differences in age indicate that the young adults are an essential target of preventive interventions. Even in several studies conducted in India, similar age distributions with highest on the second and third decades are reported and usually explained by the fact that behavioural risk factors and sexual activity increase in these age groups.

Distribution of TTIs by sex

Table 5: Distribution of TTIs by sex

Sex	HBV n (%)	HCV n (%)	HIV n (%)	Multiple n (%)	Syphilis n (%)	Total TTI n (%)
Female	1 (1.37)	2 (6.67)	4 (10.53)	1 (20.00)	0 (0.00)	8 (3.59)
Male	72 (98.63)	28 (93.33)	34 (89.47)	4 (80.00)	77 (100.00)	215 (96.41)

The concentration of TTI positivity was overwhelmingly in the male segment of donors which contributed to the donation of more than 96% of the seroreactive units. This reflects the high levels of male dominance in the donor pool but also was significant statistically when infections were categorized by type implying an actual sex based variation in risk. Male excesses of similar type have been reported in other LMIC environments and India, and they are highly likely to be connected to healthcare usage patterns gendered by occupation, greater involvement among men in higher risk behaviours, and dissimilar exposures between men and women.

Discussion

A total count of 2.96 percent of TTIs were found among seemingly healthy donors in this prospective cross-sectional study conducted in a tertiary care blood centre in Assam. This is in the range although closer to the upper end, of the range in Indian literature, where overall prevalence has range values of 1.42 2.1,[9,11]; but comparable or somewhat lower than other previous rates of around 3%. The prevalence of HBV was high (0.97), similar to national data and tertiary-level Assam data where HBV has been often the most commonly used TTI, followed by HCV or syphilis,[4,8] and both HIV (0.50) and HCV (0.40) were relatively low but still significant. A number of recent Indian series have reported still lower rates of HIV infection (0.01103), HCV infection (0.103), indicating that syphilis prevalence is improving over time at least somewhat, with some input of syphilis rates of up to 103 often and especially among urban or peri-urban populations.[911].

No malaria-reactive donors were detected, but it is also encouraging because malaria is an endemic disease in some of the East Indian regions. The most recent studies on institutions also reported zero or close to zero malaria positivity in donors, due to the ability to defer symptomatic individuals and possibly enhanced malaria control in the community, although the likelihood of transfusion-transmitted malaria houses is still existent, especially among asymptomatic individuals (even though there has been zero malaria positivity).[9,11] Nonetheless, the risk of transfusion-transmitted malaria is not removed yet, especially in the asymptomatic carriers, and where the continued alerting is still required. There is great policy interest in determining the relationship between the donor type and TTI seroprevalence. The data by Garg et al., and others showed that replacement donor population contributed more than 90% of the TTI-positive units; however, the proportion of changes at certain infections between the donor types were not statistically significant. This analysis of discrepancy with previous Indian results can have a number of explanations: the dominance of replacement donors of our sample with wide confidence intervals about estimates protecting involuntary donors; better pre-donation counselling and donor selection in either group; and a potential convergence in risk profiles with increased awareness and deferral behaviour.

Age disparities were emphatic and over fifty percent of all TTI-positive cases were in the age group 24-35 years with higher prevalence in all classes of infections. Young adulthood age peaks have been reported in rural and urban, Indian studies, and in South-Asian series wider afield,[5,6,10-13], and are thought to be associated with behavioural aspects such as unprotected sex, risks at migration and workplace. This has a public health implication that risk-reduction counselling and vaccination (of HBV) in this age group would make significant contributions to reducing TTI burden of potential donors. The percentage of male donors among the donors and TTI-positive cases was more than 93 percent and 96 percent (respectively), and the proportion of infections by sex was different significantly. It is well known in Indian and regional literature that there is a strong male-dominance in the donor source, a higher proportion of anaemia in women resulting in deferral, and that injectable drugs and risky sexual behaviour have a sex-specific spread. Another valuable approach is to increase the number of female participants in safe donation programs, although with strict eligibility requirements, as this can help increase the number of donors and and, over the long-term, can lead to higher safety. Systematically, the results confirm the further prioritisation of non-remunerated, voluntary, donor recruitment, rigorous donor education, rigorous laboratory screening with highly sensitive assays. Although ELISA-based testing is the norm in most centres in India, nucleic-acid testing (NAT) has been found to further reduce residual risk as it can identify window-period infections, but cost and infrastructure is an obstacle[3,10,15].

Limitations

This was done in one tertiary care blood centre and might not represent the rest of the population completely. No analysis of behavioural risk factors,

socio-economic status, and elaborate clinical histories were done to explore determinants of infection. There was no NAT applied and, therefore, any residual risk caused by window-period donations cannot be ruled out. Still, the great number of potential sample and the use of voluntary and replacement donors give solid modern statistics of this region.

Conclusion

The SMCH Blood Centre in Assam had almost 3 percent seroreactive apparently healthy blood donors of at least one of the major TTI with HBV and syphilis leading and none of the malaria-reactive units. The largest contribution towards infections was made by replacement donors though the type of donor was not an independent risk predictor in this data. The age (24- 35 years) and male gender were highly linked with TTI positivity, which are also important demographic intervention targets. Further eliminaton of the risk of transfusion-associated infections should be achieved by strengthening voluntary non-remunerated donor recruitment, increasing pre-donation counselling, increasing HBV vaccination, and keeping the laboratory screening of high quality and guideline-compliant, to provide a safer blood supply in North-East India.

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